

Patient Information and Surgical Consent for SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT

Confidential Patient Information

If this document is to be photocopied, the patients Name and Hospital number MUST be written on each sheet BEFORE you photocopy.

Name:				
Address:				
	I,			
*MRN:	'			
*Date of Birth:	Age:			
Male	Female			
Consultant:				
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Simultaneous Pancreas and Kidney Transplantation (SPK) is recommended for patients who suffer from diabetes and kidney failure. It is a major and complex procedure. The replacement pancreas and kidney are from someone who has died. In addition to the risk of surgery and long-term anti-rejection medication, recipients can be at risk of inadvertent transmission of cancer and infection from their donor. Potential donors are carefully assessed and screened to minimise these risks. While they can be minimised, they cannot always be prevented.

Please read this information carefully. You and your surgeon will sign it to document your consent to pancreas and kidney transplantation.

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Patient information and consent to transplantation

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you do change your mind and no longer wish to have a transplant, it is important that you inform us immediately. In that event an appointment will be made for you to discuss your decision with your primary physician prior to you being removed from the transplant waiting list.

Pancreas and kidney transplantation requires a general anaesthetic. You will have the opportunity to discuss this with the anaesthetist.

We will only carry out the surgery agreed to on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to you. However, there may be procedures you do not wish us to carry out and these can be recorded on this consent form. We are unable to guarantee that a particular person will perform your pancreas and kidney transplant. However, be assured that the person undertaking your transplant surgery will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.

About pancreas transplantation in Ireland

Pancreas transplantation is a highly specialised procedure that was first performed in the USA in 1966 with the objective of replacing the need for insulin therapy in people with Type 1 Diabetes Mellitus (T1DM).

Since then, simultaneous pancreas-kidney (SPK) transplantation has evolved both technically, and with the development of new immunosuppressive therapy. This therapy is now widely accepted as an optimal therapeutic option for patients with type 1 diabetes mellitus (T1DM) and end-stage renal disease.

St Vincent's University Hospital is home to the National Pancreas Transplant Programme which was established in 2016. The programme starts with referral of the potential recipient and follows through assessment and decision making to listing and waiting for a suitable organ.

The operation can take about 6 hours to complete. However, it may take considerably longer if the surgeons encounter any difficulties.

Patients transplanted in St Vincent's University Hospital are followed up for life jointly, by the Transplant Team and your local referring centre.

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What is the pancreas and why is it transplanted?

The normal pancreas is an organ inside the abdomen, which consists of 2 different types of tissue with 2 separate functions. Most of the pancreas is a gland that secretes a fluid rich in digestive enzymes. This helps digestion of the food we eat.

About 2-3% of the pancreas consists of endocrine tissue. These clusters of cells (islets) secrete small amounts of hormones into the bloodstream. The most important one amongst these hormones is insulin. The lack of insulin causes Type 1 diabetes. Pancreas transplants are performed to treat diabetes with severe complications.

Can all diabetic patients be treated by pancreas transplantation?

No. Only Type 1 diabetic patients who lack insulin as a result of destruction of their insulin producing islets. Such patients can be treated by pancreas transplantation.

Type II diabetes is much more common. In this disease the problem is not lack of insulin, but a resistance to the action of insulin on other tissues. Some patients with type II diabetes may require insulin injections later during the course of their disease.

In our program, pancreas transplantation is recommended only for patients with Type I Diabetes (T1DM).

What does pancreas transplantation offer to a diabetic individual?

Patients after successful pancreas transplantation do not need insulin, have no special dietary requirements, do not need to pierce themselves regularly to check their blood sugar levels and are not at any risk of becoming hypoglycaemic.

Pancreas transplantation therefore offers insulin independence and an improved quality of life, as well as a much reduced risk of diabetic complications such as;

- retinopathy leading to blindness
- neuropathy which may cause foot ulcers
- digestive problems
- abnormalities of heart rhythm
- hypoglycaemic unawareness
- · cardiovascular disease

Since the only cure for type 1 diabetes is successful pancreas transplantation, this operation should benefit diabetic patients by preventing or helping some of these long-term complications of diabetes.

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How certain are we that pancreas kidney transplantation can prevent complications?

There is still a degree of uncertainty about this. There has been no controlled clinical trial directly comparing pancreas kidney transplantation in a group of diabetic patients with insulin treatment in another comparable group of diabetic patients.

Having said this there is a substantial amount of convincing indirect evidence about the influence of successful pancreas kidney transplantation on long-term complications and survival.

There is also reasonably good evidence showing that successful pancreas transplantation can prevent or partially reverse diabetic neuropathy (nerve damage), symptoms of which include;

- fullness
- vomiting
- diarrhoea
- constipation
- tingling and numbness of hands and feet
- neuropathic ulcers of the feet
- some abnormalities of the heart rhythm
- hypoglycaemic unawareness

Retinopathy is another common complication of diabetes and is a major concern for patients since it can progress to blindness if untreated. It is likely that 5 years after transplantation, patients with retinopathy will be better off compared with those who remain on insulin.

Not all complications can be helped by pancreas kidney transplant. End stage retinopathy with blindness or significant neuropathy and vascular disease, which may have necessitated amputation, clearly represent very advanced and irreversible complications, which cannot be improved by transplantation.

Do diabetic patient receiving pancreas kidney transplant live longer?

Almost all studies have shown better long-term survival in diabetic patients who have been treated with pancreas kidney transplantation compared with those who have been treated with insulin.

Five or 10 years after transplantation the difference in the survival prospects for patients with transplants is considerably better than those who remain on insulin.

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Why don't we offer pancreas transplantation to all patients with type 1 diabetes?

Pancreas transplant brings risks as well as benefits. Lifelong treatment with insulin injections is still safer for most patients with type I diabetes.

Transplantation of the pancreas involves a major operation. Like all surgical procedures this puts the patient at risk of complications and even a small chance of death. Around 94-95% of patients undergoing pancreas kidney transplants will survive the first year after transplant.

Post-operative complications such as bleeding and infection are quite common. About 1 in 4 patients undergoing a pancreas transplant will require at least 1 more operation to deal with these complications. Sometimes the pancreas has to be removed if the patient has a very serious complication. Usually the kidney transplant gives less problems than the pancreas transplant.

Other risks relate to the anti-rejection medication that patients need to use after transplantation. These medicines (immunosuppressants) have many potentially serious side effects such as increased risk of infection and even a small increase in the probability of developing cancer. These medications are described in detail later in this document.

Even if pancreas transplantation could be made much safer, there would be the problem of shortage of organ donors to provide the number of pancreas transplants that we need to perform to meet the demand.

How successful are pancreas kidney transplants?

The success rate expressed as the probability of being cured of diabetes (not needing any insulin) 1 year after the transplant is around 85%. This is similar to the success rate of other organ transplants such as liver or heart transplants. The chance of being off dialysis at one year prost-transplant is around 96%, which is similar to kidney-alone transplant (kidney alone; 96-98% off dialysis at one year).

Beyond 1 year, patients with pancreas transplants are likely to do as well as those with other types of organ transplants.

Diabetes has caused my kidneys to fail. What does the kidney transplant involve?

If a diabetic patient has kidney failure, they can be given a pancreas and a kidney transplant in the same operation. Simultaneous pancreas kidney transplant (SPK) is particularly attractive since patients will hopefully have both their diabetes and their kidney failure treated at the same time.

Most diabetic patients in our service will be listed for simultaneous pancreas kidney transplant. In this operation, the pancreas and the kidney come from the same donor.

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The pancreas transplant is done first, and during the same operation, the kidney is transplanted second.

The surgeon then checks the pancreas again, and closes the wound(s).

The pancreas usually works straight away. We switch off the insulin infusion during the operation to check this. The kidney may take a little time to start working. There is more information about this later on in the document.

After the operation, we check to make sure the kidney is working. This may involve ultrasound or perhaps a CT scan. The doctors looking after you will decide what tests you need. Routine blood tests are often enough for us to know that the kidney and the pancreas are working well.

What about diabetic patients who do not have kidney failure, can they receive pancreas transplants?

Yes they can, but this will be appropriate in only a very small proportion of diabetic patients. As discussed above, for most diabetic patients without kidney failure lifelong treatment with insulin, despite its problems and the inconvenience, is still safer than a pancreas transplant. However a small number of diabetic patients have life threatening complications of diabetes (for example hypoglycaemic unawareness). In such patients benefits of a pancreas transplant outweigh the risks, indeed a pancreas transplant can be life saving.

What wounds will I have for a combined kidney/pancreas transplant operation?

The pancreas is placed on the right hand side of the lower abdomen. If you also require a kidney transplant it is placed on the left hand side.

How long will I be in hospital for?

This depends on each individual patient and how they recover from their operation and how well the organs function. It is usually around 14 - 21 days.

How long will I be off work?

In the early weeks after a transplant, there is a need to review patients at the outpatients clinic very frequently. Most patients will be off work for about three months, some longer.

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What tubes and drains will I have?

You will have:

- a tube (drain) from the pancreas operation site
- a tube (drain) from the kidney transplant site
- a central line (is a long fine tube used to deliver fluids and drugs)
- you will have a urinary catheter (tube placed in the body to drain and collect urine from the bladder)
- an internal stent (to help with drainage of urine until the connection between the transplanted ureter and the bladder heals)
- you will also have a nasogastric tube (a tube that is passed into your stomach via your nose).

How do you know if the pancreas is functioning?

If the pancreas functions well you will not need any insulin after your operation and your blood sugar will be normal. The ward staff will be checking your sugars for you.

Am I likely to wait longer for a pancreas compared with a kidney transplant operation?

This is not possible to predict. There are fewer pancreas donors compared with kidney donors, but there are also far fewer patients awaiting pancreas transplants, compared with the kidney transplant waiting list.

How is the pancreas allocated?

The pancreas is allocated by blood group and tissue typing which is similar to other organs. However, it will not be definite that you will receive the transplant until doctors in the transplant unit assess you to ensure you are fit and well for surgery.

We also do a crossmatch test between you and the donor. In most cases this test takes place in the donor hospital and we know the result before we call you. In some cases it requires to be performed when you come to the transplant unit. This allows us to tell if there is any reaction between you and the donor organ.

The surgeons will also need to examine the donor organs carefully to ensure there is no problem to prevent the transplant from going ahead.

What if I have a combined transplant and one organ fails?

We will usually have to remove the organ that has ceased to function if it is doing you harm. If it is not doing you harm (although no longer functioning) we can leave it in

place. At another time you may wish to be reassessed for a further transplant of the organ that is no longer functioning. The same applies for patients who have received a single transplant.

Who will perform my transplant surgery?

An appropriately experienced surgical team led by one or more consultant surgeons will carry out the pancreas and kidney transplant operation.

Before your Pancreas/combined pancreas and kidney Transplant

You have been prepared for this procedure by a team consisting of nephrologists, endocrinologists, transplant surgeons, anaesthetists, psychiatrists, dentists, transplant coordinators, paramedical and nursing staff. Your name will be added to the National Pancreatic and Kidney Transplant Waiting List. You will have already signed a consent form permitting the sharing of your personal details with the National Histocompatibility and Immunogenetics Service for Solid Organ Transplantation (NHISSOT) and the National Health Service Blood & Transplant (NHSBT), or will do so shortly.

Pancreas and kidneys are allocated to the sickest patient on the active waiting list of the correct blood group, crossmatch results and waiting time. This is why you may have to wait longer than a patient put on the list at the same time as, or even after you.

The replacement pancreas will come from a person who has died and wanted to donate his/her organs. Sometimes the process of dying may affect the pancreas and kidney, or the donor may have had an unknown medical condition that is found to have affected the organs, meaning that it is not suitable for transplant. If the donor pancreas and kidney are found to be unsuitable for you, then your operation will be cancelled. If this should happen, it will not affect your place or priority on the waiting list for another pancreas or pancreas and kidney.

When you arrive on the surgical ward, a doctor will see you and go through your medical history, examine you and take some blood for urgent tests. You will then wait until it is confirmed that the replacement pancreas and kidney looks suitable to transplant, at this point you will be told that the transplant is proceeding. At the appropriate time you will be prepared and taken to the theatre for the transplant operation.

If you are on haemodialysis, you may need dialysis prior to the operation. This will be decided by the consultant transplant nephrologist, who may discuss you with the consultant anaesthetist. Although you may have a routine dialysis session, out of hours it may be done in intensive care. This is because more staff and equipment are available there at night and weekends.

If you are using peritoneal dialysis, you will need to bring in all your equipment and fluids with you to the ward. You will need to continue peritoneal dialysis until it is confirmed that the operation is definitely going ahead. You will need to empty out all

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your fluid just before you go to the operating theatre. During the operation, the PD tube will be removed. This is because it won't be usable afterwards, and could get badly infected.

If the operation is cancelled, you should restart your peritoneal dialysis right away.

If you are a woman of childbearing age, we will perform a pregnancy test on the ward prior to your operation. If you were pregnant, we would not be able to perform your transplant. Although your doctors can discuss risks and benefits with you, it is usually most unwise to consider pregnancy in the first year after a transplant, as there are significant risks to you, the transplanted organs and the baby. The medications are also dangerous for an unborn baby.

Later, when you are recovered, a change can be made to medications to allow patients to have safe and successful pregnancies. If you become pregnant on the waiting list, you should inform the transplant team straight away. If you become pregnant after transplantation, you should inform the transplant team straight away. Any pregnancy in a transplant patient requires more careful management by specialists in the transplant team and the obstetrics team than for non-transplant patients.

We appreciate how anxious this stage can be for everyone but we ask for your patience as we prepare you for your operation and wait for news regarding the donor pancreas and kidney's suitability for transplant.

During your Pancreas or pancreas and kidney Transplant

In exceptional circumstances we may encounter a problem during the transplant operation that makes it unsafe to continue. This may be because of technical difficulties during your operation, or due to new and unexpected findings with you or with the new organ(s). If that happens your operation will be stopped and you will be woken up and returned to the ward.

During surgery you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. A blood transfusion involves giving you other blood or components such as plasma or platelets that are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend you have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. Your doctor can explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment.

Simultaneous pancreas and kidney transplantation also involves the use of general anaesthesia. For your information a summary of what will happen is given below:

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You will be given intravenous medication to help you relax and an oxygen mask will be placed over your mouth and nose. Once you have drifted off to sleep, a tube will be placed in your mouth and down into your lungs. This is then attached to a breathing machine. We will then place several lines (tubes/cannulas) into blood vessels in your arms and neck. These enable us to give you fluids and/or blood and help us take blood for tests, and monitor your condition during and after the transplant. In addition, once you are asleep, a tube will be passed into your stomach through your nose to empty (decompress) your stomach. We also place a tube (a urinary catheter) into your bladder during the operation, so that we can closely monitor your urine production.

Once you are asleep, a team of surgeons will carry out the pancreas and kidney transplant procedure. The replacement donor pancreas and kidney will be transplanted by joining up the blood vessels to each organ, and joining the pancreas to the bowel, and tube that drains urine from the kidney (ureter) to the bladder. The join of the ureter to the bladder may be made over a little plastic tube called a stent. This prevents undue narrowing of the join by scar tissue. The stent is removed a few weeks after the transplant by a simple camera going into the bladder to remove it.

Two drains are usually inserted into the abdomen and left there to allow blood and fluid to drain from the transplant site. They are usually removed after a few days.

After your Transplant

Once your surgery is completed, you will be taken to the Intensive Care Unit (ICU) or high dependency unit (HDU). You will be woken up and removed from the ventilator (breathing machine) as soon as the Anaesthetist/Intensivist in charge of your care decides it is safe to do so. Patients are woken up immediately after transplant or the next day.

Life Style issues after Transplant. In the days after your transplant you will be given more detailed information about any special measures you need to take after your surgery. Prior to your discharge, we will also invite you and your family to meet with the transplant co-ordinators to discuss and plan how your recovery will continue at home.

At that time you will be given information about things to watch out for that might be an early sign of problems (for example, infection) and will give you clear advice on what to do if you encounter any such issues. Some of the more frequently asked questions are answered below:

Eating and drinking. You will be slowly re-introduced to fluids and then food over the first few days after the operation. Often, the bowel goes to sleep after the operation, and we can't feed you properly because you are feeling or being sick. If this is an issue for you, we may think about feeding into a vein ('TPN') for a few days while the bowel recovers.

Getting about after the operation. We will encourage you to move around and carry out deep breathing exercises as soon as you are able to do so. This both reduces

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the chance of getting a blood clot in the leg and also helps you to avoid chest infections.

Nausea and Vomiting. Some people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.

Such sickness is more common if you have a condition called 'autonomic neuropathy', which is a complication of diabetes. In this situation, the patient feels better if the stomach is kept empty, and we may do this by leaving a tube down the nose into the stomach. Nobody likes this much, but it's better than being sick. We will take it out as soon as we can. It's usually no more than 1-3 days.

Leaving hospital. Following a pancreas or pancreas and kidney transplant, you are likely to need to stay in hospital for 14 to 21 days. In some circumstances you might need to stay longer, depending on your clinical condition and your doctor's opinion.

Follow up in Out-patients. Once you are home after the operation, you will be seen in the transplant out-patient clinic to check your progress and to make sure your new pancreas and kidney are functioning well. Initially this will be one to three times a week. Once you are clinically stable, the interval between clinic visits will increase. For those who live far from the unit, we will agree a plan which enables you to have safe care between the transplant unit and your local nephrologist.

Fluid intake at home

You will need to measure how much fluid you are drinking every day. You should write down how much you drink in a daily diary. This is very important, as the doctors will tell you to drink so many litres per day. We will make sure that you are able to drink these volumes before you leave the hospital. This can be very hard for patients who are used to drinking very little. However, not drinking enough can seriously damage the new kidney. If you can't drink enough fluid at home, you need to call the coordinator immediately so that we can help you.

Daily Weights at home

You will need to weigh yourself every day at home at the same time every day. Most patients find that first thing in the morning after you have emptied your bladder is a good time. You should write your weights down in your daily diary, and bring the diary to show any doctors who are looking after you. We ask you to do this as it tells us how much fluid your new kidney is holding onto and how much it is passing.

Urine volumes at home.

Patients need to keep an accurate measure (with a measuring jug) of how much urine they pass each day. A plastic measuring jug is easiest to use and to keep clean. These volumes need to be written into your daily diary.

Sugars

Patients in the early post-operative phase will check their sugars twice a day. Once before breakfast and once before bed. This should be added to the daily diary. Sugars can be up and down a little, especially early on. However, if your blood sugars

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suddenly go up, you should call the coordinator straight away. If your sugars are 10 or more at any time, you should contact the coordinator to seek advice.

All of the measuring and weighing seems like hard work. This period of postoperative care passes quickly, and your doctors will tell you how long you need to keep up the measurements, usually only a few weeks for most of them.

It's all worthwhile in the end.

Resuming normal activities including work. When you leave hospital, you should be able to carry out light daily activities at home. However, it might be a few months before you can return to normal active work. You will have a lot of clinic visits to start with, and your wounds need to heal properly. You also need to recover fully as a person from a major event in your life.

Transplant patients are at increased risk of infection. The risk is highest early on. Just after transplant, you should avoid anyone who has an obvious infection, like chicken pox or a cold. Very small children often have viral infections and in general terms, it is wise to avoid areas where there are large numbers of very young children such as nurseries and the like.

Certain fungi in the environment pose greater risks. Some are more common in agriculture and on building sites; indeed anywhere that dust is being generated. It is wise to avoid dusty environments in the early months after transplant. Your transplant team can advise you about any specific issues you may have.

Significant, unavoidable or frequently occurring risks associated with Transplantation

Pancreas and kidney transplantation is a complex and major procedure with a high chance of success. Unfortunately, about 5 in 100 recipients will die in the first year following pancreas and kidney transplantation. A very small proportion may die during the operation itself (less than 1 in 100).

Early complications

Following the operation, there is a small risk the donor organs may never function. For both pancreas and kidney, this is about 1 - 2 in 100.

The pancreas is joined to the bowel to drain away all the normal secretions that the new pancreas makes. In up to 15 in 100 cases, a severe infection can occur near the join. The patient may need re-operation urgently to assess the situation. If the join has leaked, the bowel content contains a lot of bacteria, and infection rapidly follows. The surgeon usually has to remove the pancreas in this situation.

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This is because the leaking bowel won't heal and keeps leaking, making the infection even worse. The surgeon only removes the pancreas if nothing else can be done. This kind of infection can be a risk to the patient's life if left untreated, and so the surgeon may have to do what is required to save the patient. If pancreas removal is a possibility, this will be discussed with you before re-operation and discussed with you after the operation.

It is very hard for the patient if the pancreas is taken out, as the patient will require insulin again and is diabetic again. However, the surgeon will only do this if your life is in danger from the pancreas transplant. The kidney is left alone.

There is also a risk of pancreatitis, which is when the new pancreas becomes inflamed. This may be trivial, but it can be a significant problem leading the surgeon to re-operate and check that the pancreas is still okay. If the pancreas is a danger to you and is making you very ill, the surgeon may have to remove the pancreas.

Aside from infection, there is a 15 in 100 chance that the blood vessels or raw surfaces bleed after the transplant, and you might need re-operation to stop the bleeding.

Instead of bleeding, a new pancreas has a small chance (about 5 in 100) of forming a blood clot in the vein attaching the pancreas to the body. This rapidly causes the pancreas to stop working properly. When the transplant team see that there is a problem, a CT scan is performed which shows the blood clot in the vein. Almost always, the pancreas has to be removed as the tissue can't survive with a blocked vein.

Overall there is a 25-30 in 100 chance that you would need a second operation within the first month to correct a pancreas problem that has occurred after the transplant.

From the kidney point of view, there is often a delay with the start of the kidney working (up to 40 in 100 transplants). It is quite common for the kidney to take a week or so to start working. This may mean that dialysis is required in the short-term, even in patients that have not previously required dialysis. If the kidney is a little slow to work, we may carry out a needle biopsy to check the kidney tissue under the microscope. This is to make sure there is no rejection or infection.

About 10-20% of patients will develop early rejection, so this needle test (biopsy) is an important test. It is done with local anaesthetic by a specialist who is experienced in kidney biopsy. If there is rejection, your transplant team consultants will decide how it should be treated. It is most often treated by stronger immune suppressants (anti-rejection medications) given through a drip. A further biopsy may be required to check the rejection has been treated successfully.

Occasionally, very strong anti-rejection medication is required which means you will need to be looked after in a special room by yourself. The staff may need to wear gowns and masks. They will explain everything to you and keep you informed about how your pancreas and kidney are doing.

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Any patient having a kidney transplant can develop a leak from the join with the bladder. On many occasions, the join heals up without the need for surgery. It does mean that a fine tube (drain) needs to be left in longer after the operation, or perhaps a new one needs to be put in by a specialist in the x-ray department. Often, we also need to leave the bladder catheter in longer too.

Sometimes, there is no option but to perform an operation to repair the join.

On occasion, the tube draining urine from the kidney can become scarred and narrowed, preventing the normal drainage of urine from the kidney. In this situation, the kidney becomes swollen ('hydronephrosis') and a drain needs to be placed into the kidney to relieve the swelling (nephrostomy). Sometimes we find a reversible reason for this, and no operation is required. However, an operation may be needed if nothing else can be done. The transplant team will work out the best treatment for you and discuss with you. Sometimes, a patient isn't strong enough for more surgery, and we wait until the patient is in better health before trying to fix such problems.

From time to time, lymphatic fluid can collect near the kidney. This happens when very fine tubes conducting lymph are disturbed during the transplant. This fluid can collect and form a swelling which squeezes the kidney, and may take several weeks to appear. This swelling may have no effect, but may equally block off the tube draining urine from the kidney or even narrow the blood vessels. In these cases, we need to drain the fluid, usually with an operation.

As with any other operation, complications can occur such as wound infections, chest infections, urine infections, fluid leaks from drains and wound sites etc.

Serious problems, such as blood clots in the legs and lungs (1 -2 in 100), as well as blood clots in the vessels of the heart or vessels of the brain, causing heart attack or stroke are also possible. Although patients are very carefully assessed to reduce the risk of these complications, we can't reduce the risk to zero.

These complications are managed with medication and time, rather than any further surgical procedures.

Summary

All of the above issues give rise to a risk of re-operation for the pancreas of up to 25-30 in 100, and re-operation for the kidney of less than 5 in 100, over the first year. The chance of surviving the first year is 94-95%, with an 85% chance of having a working pancreas and a 96% chance of having a working kidney.

Later complications

Later on, there is still a chance of developing acute rejection (20 in 100 overall) of the replacement kidney and/or pancreas. This sort of rejection is usually easy to treat with an extra course of powerful medication, but will require you to be in hospital for three or four days. In the longer term, a small minority of people develop chronic rejection of the replacement pancreas or pancreas and kidney. This is different from

acute rejection and is more difficult to treat; sometimes it requires another kidney transplant to replace the organ that has been rejected.

The infection risk is still present later on. We will provide you with protective medication for the first 3-6 months if you are at risk of specific infections such as CMV. Your transplant doctors can explain if this is relevant to you. All patients receive protective medication for PJP (previously known as PCP).

Most people who have had a pancreas and kidney transplant need to undergo further admissions to hospital in the subsequent months and years. These are necessary to correct any medical problems that might arise and so keep you and your organs as fit as possible. During these admissions you might have more blood tests, scans, endoscopies and/or biopsies.

You will need to take a number of medications on a long-term basis to prevent rejection of the new organ(s). This is called immunosuppression or antirejection medication. It is important to realise that if you stop the antirejection medicines you may lose your new pancreas /pancreas and kidney. If you feel that you will not be able to adhere to a medication regimen for the rest of your life you should tell your health care professional now.

The Donor pancreas and kidney

It is important that you appreciate that transplantation involves taking a risk. However, you should remember that your doctors have put you on the transplant waiting list because they believe that the risks of a transplant are less than the risks to your life if you did not have one. The following section is about the donor organ(s) and highlights some of the risks of transplantation.

Although the organ(s) you receive are new to you, it is not a new organ. The pancreas and kidney have come from someone who has died and wanted to donate their organs to help someone after their death. It is uncommon for a young patient to be an organ donor, or for the donor to die of an accident; he/she usually dies of a medical condition such as a stroke, brain haemorrhage or heart attack. The average age of an organ donor in Ireland is increasing and in 2014 it was 55, with some donors aged up to 80. Half of all organ donors are smokers or ex-smokers and many of them will have drunk alcohol.

Some donors have medical problems that we do not know about at the time of death and which might be transmitted to you. We make every effort to check carefully all organ donors for the presence of infections such as HIV AIDS or hepatitis that may be transmitted with the organ(s). Nevertheless, some donors may have viral infections that either we do not know about or which we believe represent a low risk to you as a recipient (for example cytomegalovirus, which we can readily treat after the transplant). The risks of you catching a life threatening infection are small (less than 1 in 100).

Some donors may have, or have had in the past, serious viral infections. Examples would include donors who have previously had hepatitis B infection from which they are now clear. Such pancreas or pancreas and kidneys can be safely

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transplanted by giving additional medication after transplantation to prevent hepatitis B occurrence in the recipient. Donors with hepatitis C are sometimes considered, and, if used, would be transplanted into people who already have hepatitis C.

Some donors are known to have taken intravenous drugs or shown other behaviour that increases their chance of having a hepatitis virus or HIV. We carefully check all donors for these viruses but there is a small chance (1 or 2 in 1000) that an infection in a high risk donor such as these may be missed and therefore transmitted to the recipient. If one were transmitted inadvertently, you would need to take anti-viral drugs for the rest of your life, in addition to immunosuppression.

Approximately 1 in 2000 donors has a cancer that we do not know about, and which is passed on with the transplant. This is often a fatal complication. Unfortunately we cannot predict which donors may have a hidden cancer and when this might occur.

Around 2 in 100 donors have died from a cancer in the brain. Such cancers rarely spread outside the brain so it is common for transplant doctors to transplant organs from such donors. Nevertheless, there is a small chance (around 2 in 1000) that, if your donor had a brain cancer, it might be passed on to you. If you do not wish to take this risk let your doctor know and indicate your wish on the consent form so that you will not be called in for a pancreas or pancreas and kidney from such a donor.

Some donors may have a cancer treated in the past and are thought to be cured of it. We make every effort to get all the details of these cancers and the treatment before deciding that the organs are safe to use. No cancers have been transmitted from such donors in Ireland or the UK, but there is a small risk that this may happen.

Heart beating & Non heart beating donors. The vast majority of organ donors in Ireland are confirmed to be dead by testing the brain function while they are on a ventilator and while their heart is still beating; these are brain dead donors. Others have irreversible brain damage but are not brain dead. Nevertheless the brain damage is such that they will not recover so treatment, including ventilation is stopped and as a result their heart stops; these are called circulatory death donors (DCD) or non-heart beating donors. While almost half of all dead donors in the UK (42% in 2012) were circulatory death donors the number of non-heart beating donors in Ireland is currently very small.

Pancreas and kidneys from DCD's have a slightly higher chance of not working after transplantation (3 in 100 instead of 1 in 100). There is also a higher chance of the pancreas and kidney not being suitable for transplant resulting in a "false alarm" call. Pancreas and kidneys from non-heart beating donors are considered to be "marginal organs", i.e. organs that are not quite as good as standard cadaveric grafts. To date there has been a moderate amount of experience of using DCD pancreas and kidneys in the UK. The results have been very promising and patient survival rates are similar to that of heart beating grafts with 85% graft pancreas survival at one year.

However if you do not wish to receive a pancreas and kidney from a donor following circulatory death, please let your doctor know and indicate your

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decision on the consent form. This option is not suitable for everyone; however there is an advantage in being considered for all donor offers. Broadening the donor pool can shorten the time a recipient spends waiting for a transplant thus reducing your chances of dying while on the waiting list.

The best pancreas and kidney for you

It is important to remember that we will only ever use a donor pancreas and kidney that we think will work and will give you long, life-supporting function. When allocating a pancreas and kidney to you for transplant we believe it will give you the best chance of life and reduce your chance of dying on the waiting list. This involves balancing the risks associated with a donor to how sick you are now or may become in the future.

Drugs

In order to protect the transplanted pancreas and kidney from attack (rejection) by your immune system, you need to take immunosuppressant medications. It is common for drugs like these to be used in combinations or conditions for which they were not originally licensed. This is common practice in transplant units such as ours.

Problems with immunosuppression

Although immunosuppression regimens may cause some complications, you must keep taking these medications or risk losing your new pancreas or pancreas and kidney to rejection. If this happens you may not be considered for a replacement.

While immunosuppression drugs protect your new pancreas or pancreas and kidney, they also reduce your ability to fight infections, particularly from viruses. If you are considered to be at risk of a viral infection, such as cytomegalovirus (CMV), you will be given a course of treatment after the transplant to prevent this. You will also be encouraged to have an annual flu vaccination, to reduce your chances of becoming unwell with a 'flu virus.

The immunosuppressive medication that you will need to take may increase your chance of developing cancer. Some cancers are more common in transplant patients. Around 2 in 100 patients may develop a cancer of the lymph glands (lymphoma), which would require treatment and which can be fatal. Skin cancer is also common, particularly if you have spent your life working outdoors. To reduce your chance of skin cancer you will be advised to wear a sun block cream whenever you are out in the sun, and cover up where possible.

As with other drugs, immunosuppressive drugs all have side effects. These include causing kidney damage, diabetes, stomach upset and wound infections. To reduce any side effects, the medical team will carefully monitor and adjust the dose of medications you take. This is done on an individual basis and it is worth remembering that in some cases alternative medication may be available should you encounter major problems.

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It is very important that you follow our instructions on when and how to take your medication. If you do not follow the dosage schedule strictly (for example you miss taking tablets), you run a significant risk of losing your pancreas or pancreas and kidney from rejection, without the prospect of a new one.

Other drugs

Some patients who require pancreas or pancreas and kidney transplantation may need to take antiviral drugs following transplantation. This treatment will continue for life.

Concerns

We are sorry if the detailed information that you have just read appears frightening. It is important that you appreciate that pancreas and kidney transplantation has its risks and that we cannot offer any individual guarantees about success. Nevertheless, you should remember that the Transplant Multi-Disciplinary Team (MDT) has recommended pancreas and kidney transplant for you because they believe that the benefits will greatly outweigh the risks in your case.

Information and support

If you have any further anxieties or questions, please feel free to ask any member of the Transplant Team. Further information can be obtained from the Pancreatic Transplant Coordinators who can be reached on (01) 221 3358 or through the switchboard on (01)221 4000.

Anaesthesia

During your assessment you will have met with members of the anaesthetic team and will have had an opportunity to ask any questions you may have about this aspect of your pancreas or pancreas and kidney transplant. You will also be aware that in order to undergo a pancreas and kidney transplant you will require a general anaesthetic.

Before your pancreas and kidney transplant

During your pre-operative consultation, you will meet a transplant anaesthetist who will discuss both the type of anaesthetic you will require and pain relief after your surgery. To inform this decision, he/she will need to know about:

- Your general health, including previous and current health problems
- Whether you or anyone in your family has had problems with anaesthetics
- Any medicines or drugs you use prescribed or not
- Whether you smoke
- Whether you have had any abnormal reactions to any drugs or have any other allergies
- Your teeth; whether you wear dentures, or have caps or crowns

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck; he/she will look at all your test results.

Pre medication

You may be prescribed a "pre-med" prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery. It can provide pain relief, reduce the risk of you being sick or treat a specific medical condition that you may have. Not all patients will be given a pre-med or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.

Moving to the operating room or theatre

You will be asked to change into a gown before you leave the ward and you will be taken to the operating suite. When you arrive in the theatre or anaesthetic room, the medical team — usually the anaesthetic nurse, will perform a check of your name, personal details and confirm the operation you are scheduled to have. Monitoring devices will be attached to you, including a blood pressure cuff, heart monitor (ECG) and a clip on your finger to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted and you will be asked to breathe oxygen through a face mask.

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General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything that happens during this time. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring vital signs such as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthesia and operation you have had, how much pain relieving medicine you need and your general health. Immediately after a transplant most patients are kept anaesthetised for several hours on the intensive care unit. When you wake up you will be conscious of the breathing tube in your mouth, which the nurses will remove when you are fully alert.

Most people will feel sleepy after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (10 in 100 people) and common side effects (1 in 100 people)

Feeling sick and vomiting after surgery

Sore throat

Chest infection

Dizziness, blurred vision

Headache

Bladder problems

Damage to lips or tongue (usually minor)

Itching

Aches, pain and backache

Pain during injection of drugs

Bruising and soreness

Confusion or memory loss

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Uncommon side effects and complications (1 in 1000 people)

Heart attack or stroke

Muscle pains

Slow breathing (depressed respiration)

Damage to teeth

An existing medical condition getting worse

Awareness (becoming conscious during your operation)

Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications

Damage to the eyes

Serious allergy to

drugs Nerve damage

Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about 5 deaths for every million anaesthetics in the UK.

For more information about anaesthesia, please visit the College of Anaesthetists of Ireland website: www.anaesthesia,ie or the Royal College of Anaesthetists' website: www.rcoa.ac.uk

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Information about important questions on the consent form

1 Creutzfeldt Jakob Disease ("CJD")

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation and to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment; they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical/nursing and other healthcare staff. You do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in Training

Training doctors, nurses and other health professionals is essential to the health service. Your treatment may provide an important opportunity for such training but would always take place under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students. This will not affect your care and treatment.

4 Use of Tissue

As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards.

In order to carry out research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to participate in research this will not in any way affect the care and treatment we provide.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact the transplant co-ordinators.

We are now a smoke free site; smoking will not be allowed anywhere on the hospital site. For advice and support in quitting contact the smoking cessation service

Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN:

AFFIX SMALL PATIENT LABEL HERE

Consent of Patient or Person with parental responsibility

At the time of my inclusion of the National Waiting List, I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: Please read the patient information and when you are sure, **sign your initials** in the relevant boxes to answer the following questions:

1	Creutzfeldt Jakob Disease (CJD)	Yes	No
at rish health If Y	you ever been notified that you are k of CJD or Variant CJD for public purposes? es, please inform your health ssional		
2	Photography, Audio or Visual Recording	Yes	No
types diagnormal I agree of the audit	the to the use of any of the above of recordings for the purpose of cosis and treatment the to unidentified versions of any above recordings being used for and medical teaching in a care setting		
3	Students in Training	Yes	No
nursir	te to the involvement of medical, and other students as part of formal training		
4	Use of Tissue	Yes	No
blood diagn and resear	agree that tissue (including) not needed for my own osis or treatment can be used stored for ethically approved rch which may include ethically ved genetic research		

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i alic	nt Information and Surgical Consent for			
	PANCREAS KIDNEY TRANSPLANT	PATIENT NAME: MRN: AFFIX SMA		
		MININ. ALLIA OMA	I AILNI E	ABLL HERE
information purportion	There additional clinical mation is needed for the oses of ethically approved rch, I agree that relevant ons of my medical record may ooked at by researchers or by ant regulatory authorities. I give ission for these individuals to access to my records.		Yes	No
5	Donor specific choices			
	onsider appropriate for you taking int			
donor wish book remer	onsider appropriate for you taking inter offer. This will be done unless you to consider. A full explanation of the let. If you indicate you do not wimber that you reduce your chance of se initial the box THAT INDIC of donor described	u indicate donor types ese donor choices is giv ish a particular type of receiving a pancreas an	below that yen in the in of donor y d kidney.	you don't nformation ou should
donor wish book remer	r offer. This will be done unless you to consider. A full explanation of the let. If you indicate you do not wimber that you reduce your chance of se initial the box THAT INDIC	u indicate donor types ese donor choices is given ish a particular type of receiving a pancreas and CATES YOUR DE	below that yen in the in of donor y d kidney.	you don't nformation ou should
donor wish book remer Pleas type a I wish brain are constant of the property	r offer. This will be done unless you to consider. A full explanation of the let. If you indicate you do not wimber that you reduce your chance of se initial the box THAT INDIC of donor described	u indicate donor types ese donor choices is giv ish a particular type of receiving a pancreas an CATES YOUR DE beating Donor) from a donor after Y the majority of donors ain function while they	below that yen in the in of donor y d kidney.	you don't nformation ou should
donor wish book remer Pleas type a I wish brain are contained are st	r offer. This will be done unless you to consider. A full explanation of the let. If you indicate you do not wimber that you reduce your chance of se initial the box THAT INDIC of donor described Donor after Brain Death (Heart-let) to receive a pancreas and kidney a death. I understand that in Ireland the onfirmed to be dead by testing the brain to consider the confirmed to be dead by testing the brain to consider the confirmed to be dead by testing the brain to consider the confirmed to be dead by testing the brain to consider the consideration of	u indicate donor types ese donor choices is given ish a particular type of receiving a pancreas and CATES YOUR DED. beating Donor) from a donor after Yellow the majority of donors ain function while they ret is still beating.	below that yen in the in of donor y d kidney. CCISION	you don't nformation ou should from the

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Patien	Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT PATIENT NAME: MRN: AFFIX SMALL PATIENT LABEL HER				
C	Donor who has died from a brain	cancer			
has d small	n to receive a pancreas and kidney fied from a brain cancer, although I is (less than 2 in 100) chance of the can. I understand that 2 in 100 donors have	Yes	No		
d	Donor who has a history of cancer				
has a very s	n to receive a pancreas and kidney for the history of cancer, although I understand (less than 1 in 100) chance of the nitted to me.	Yes	No		
e	Donor known to use intravenous drisk of viral infections	rugs or wh	ose behavi	our puts t	hem at
know them sugge	h to receive a pancreas and kidn n to use intravenous drugs or whos at risk of viral infections even thoug st that I would have less than 2 in 100 ed and need to take anti-viral drugs as	Yes	No		
6	The following operative risks have and I understand:	e been disc	ussed	Yes	No
Pa	survival rates: ncreas (85 in 100 people at 1 year), dney (94 in 100 people at 1 year)				
	unctioning kidney or pancreas transplantioning kidney or pancreas never works)				
(up to	red Kidney Graft Function: 40 in one hundred deceased donor true is a delay in the start of the kidney was term dialysis may be required	-			

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Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN: AFFIX SM		
The following operative risks have been discussed and I understand:	Yes	No
Infection/leak with re-operation (up to 15 in 100 people)		
Bleeding requiring re-operation (up to 15 in 100 people)		
Pancreatitis		
Urine leak (2 in 100 people)		
Thrombosis (blood clot in the vessels, causing the kidney or the pancreas not to work)		
Episode of rejection after transplant, requiring treatment (in up to 20 out of 100 people)		
Cardiac complications		
Blood clots in the legs (DVT) or lungs (PE) (1 in 100 people)		
Mortality (less than 5 in 100 people)		
7 The following aspects and risks of simultaneous pancreas kidney transplantation have been discussed and I understand:	Yes	No
Appendicectomy at the time of transplant		
Donor specific risks were discussed, including transmissible infection (such as cytomegalovirus), or malignancy (known/unknown)		
Immunosuppressive treatment was discussed, including its associated risks (such as drug side effects, infection, diabetes and cancer, including skin cancer)		
The process of long-term follow-up post-transplantation and the consequences of not following medical advice on graft survival was discussed		
I have an understanding of current graft survival and mortality rates		

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Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN:

CONSENT FORM

I consent to Simultaneous Pancreas and Kidney

Transplan	tation and to the use of the donor type	indicated
This also includes procedure such as Blood Transfe		uring the
Other procedu	ure (please state)	
		-
An information so person	ession has been attended by the Patient and their desig	nated support
Yes	Date	
No	Rationale	
The Transplant Pa	rocedure will involve:	
General and/o	r regional anaesthesia	
Consultants Signa	ature (SVUH)	
Medical Council	Number	_
Date	Time	
Consultants Signa	ature (Beaumont)	
Medical Council	Number	_
Date	Time	

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Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN:

AFFIX SMALL PATIENT LABEL

HER

I have read and understood the Patient Information about this surgery and the above additional information. I consent to Transplantation and to the use of the donors indicated above.

donors indicated above.
Name of patient (PRINT):
Signed (Patient):
Date:
If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Name of witness (PRINT):
Signed (Witness):
Date:
Confirmation of consent AT THE TIME OF TRANSPLANT BY CONSULTANT OR SPECIALIST REGISTRAR
Confirmation of consent (where the treatment/procedure has been discussed in advance). On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the transplant surgery to go ahead. Name (PRINT):
Signature:
Medical Council Number:
Date:
Please confirm all sections have been completed

Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN: AFFIX SMALL PATIENT LABEL

Interpreter's statement (if appropriate): I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand: Date: ___/___/ **Signed** (Interpreter): Withdrawal of patient consent The patient has withdrawn consent (ask patient to sign and date here): Date: ___/__/___ **Signed** (Patient): Date: ____/___ **Signed** (Health Professional): Name (PRINT): Job Title **IMC** Number

Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN:

AFFIX SMALL PATIENT LABEL HERE

CONSENT FORM REVIEW

Following discussion at time of inclusion on the National Waiting List, consent for simultaneous kidney pancreas transplantation is reaffirmed every 12 months where possible

Date	Any further information discussed not detailed above	Patient (sign & print)	Clinician (sign & print)

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Patient Information and Surgical Consent for PANCREAS KIDNEY TRANSPLANT

PATIENT NAME:

MRN:

AFFIX SMALL PATIENT LABEL

High	Surgica	al Risk		_	
Yes		No			
Assessment Sheet					

Pancreas and kidney Transplant Surgical Summary Sheet

Date of Assessment:		Assessi	ng Surge	on:	
Patient Name:		_ MRN_			
Recipient small body size: Ye	es	No			
Height: Weight:		BMI:			
Previous Surgical History					
Previous Pancreas or pancreas an	d kidney	Surgery:	Y	Zes .	No
Specify:	=				
Previous Abdominal Surgery: Y	es	No			
If Yes, Type of Surgery:			Patholog	gy:	
Abdominal Imaging					
Adequate Imaging Available: Ye Further Imaging Required: Imaging Assessed: Other Abnormality:	Yes CT Yes	MRI			
Consultant Surgeon:			_		Further Considerations

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PANCREAS KIDNEY TRANSPLANT	MRN: AFFIX SMALL PATIENT LABEL HERE

Notes: