

# Australian and New Zealand Paired Kidney Exchange Program

Protocol 1: ANZKX Protocol



## Introduction

The Australian and New Zealand Paired Kidney Exchange (ANZKX) Program is a collaborative trans-Tasman live kidney donor program involving transplanting centres in Australia and New Zealand. The goal of ANZKX is to increase live kidney donor transplants by identifying matches for incompatible donor-recipient pairs. Consistency across all centres is essential for the success of the program.

For the purpose of recruiting and assessing donor-recipient pairs, the following transplant centres have been identified to participate in ANZKX.

For the purpose of donor retrieval surgery the transplant centres listed below have been identified to perform a sufficiently large number of living donor surgeries per annum to meet the criteria recommended by the Transplantation Society of Australia and New Zealand (TSANZ) Donor Surgeons Donor Coordinators Advisory Committee.

Australian participating centres:

State	Transplant Centre	Retrieval Transplant Centre
<b>New South Wales</b>	Westmead Hospital The Children's Hospital at Westmead Royal Prince Alfred Hospital Prince of Wales Hospital Sydney Children's Hospital Royal North Shore Hospital St Vincent's Hospital John Hunter Hospital	Westmead Hospital Royal Prince Alfred Hospital Prince of Wales Hospital Royal North Shore Hospital John Hunter Hospital
<b>Queensland</b>	Princess Alexandra Hospital Mater Children's Hospital	Princess Alexandra Hospital
<b>South Australia</b>	Royal Adelaide Hospital The Women's and Children's Hospital	Royal Adelaide Hospital
<b>Victoria</b>	Royal Melbourne Hospital Royal Children's Hospital Monash Medical Centre Monash Medical Centre (paediatric) Austin Hospital St. Vincent's Hospital Alfred Hospital	Royal Melbourne Hospital Monash Medical Centre Austin Hospital Alfred Hospital
<b>Western Australia</b>	Sir Charles Gairdner Hospital Fiona Stanley Hospital Princess Margaret Hospital	Sir Charles Gairdner Hospital Fiona Stanley Hospital

New Zealand participating centres:

Transplant Centre	Retrieval Transplant Centre
Auckland City Hospital Christchurch Hospital Wellington Regional Hospital	Auckland City Hospital Christchurch Hospital Wellington Regional Hospital

The purpose of this document is to inform transplant centres performing donor nephrectomies, those performing the transplant in the recipient, renal specialists, tissue typing laboratories, the OrganMatch and jurisdictional stakeholders of the Protocol for the ANZKX Program.



The ANZKX Protocol consists of 2 specific parts:

**Part 1:** General Principles and Structure of the ANZKX Program

**Part 2:** Process of the ANZKX Program

Prior to the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program, the Australian Paired Kidney Exchange Program (AKX) *General Principles* were initially developed by the National Paired Kidney Exchange Program Advisory Group: An advisory group of the National Cognate Committee on Organ & Tissue Donation & Transplantation in Australia. Modifications to these original Principles and Protocol, including the development of the ANZKX Program Protocol, have been made and reviewed by the RTAC/ANZKX Clinical Oversight Subcommittee (RACOS) and the Renal Transplant Advisory Committee (RTAC).



# Part 1: General Principles and Structure of the ANZKX Program

## ANZKX general principles

- 1 ANZKX will follow international, Australian, and New Zealand best practice in living kidney donation and transplantation.
- 2 ANZKX will be governed by principles of good governance involving transparency, accountability and equity whereby the management and operation of ANZKX complies with ethical, financial, and legislative requirements, as well as relevant policy and frameworks.
- 3 ANZKX will support ethical practice, including upholding respect for donors, ensuring equity in allocation of organs, and maximising benefits of paired kidney exchange to recipients.
- 4 ANZKX will protect the interests and well-being of participants by:
  - placing paramount importance on the safety and interests of the donors and recipients;
  - using recruitment methods that are non-coercive, equitable and respectful of individual freedom of choice;
  - ensuring that participation of donors and recipients is based on voluntary and informed consent;
  - informing participants of their right to withdraw from the Program at any time, for any or no reason, and any implications of doing so
  - undertaking any reasonable step to protect the confidentiality and privacy of donors and recipients.
- 5 When donor operations are occurring on the same day, ANZKX will aim for simultaneous anaesthetic induction time (AIT), unless this is not practical due to logistics or cold ischaemic times. Chains involving an exchange between Australia and New Zealand are more likely to have non-simultaneous donor AIT. This will be decided on a case-by-case basis.
- 6 Non-directed altruistic chain surgeries may be scheduled on different days with the use of bridge donors. The surgeries must occur in order with the recipient receiving a kidney prior to their registered donor donating. Transplants within a closed exchange (containing 2 or more pairs with no non-directed altruistic donor) will always be performed on the same day.
- 7 For optimal operation, ANZKX will rely upon centralised coordination, and cooperation between participating transplantation centres, tissue typing laboratories and the ANZKX Coordination Centre.
- 8 ANZKX seeks to increase overall numbers of living kidney transplants. In selecting which transplants to undertake, ANZKX (with clinical oversight from RACOS) will also take into account the disadvantage in opportunities for successful transplantation generally experienced by O blood group and immunologically sensitised individuals.

## Responsibilities and obligations of participating transplant units

Participating Hospitals should follow the protocols detailed in the ANZKX User Manual, including but not limited to the following requirements:

- Inform persons associated with participation in the ANZKX Program (such as hospital executives, nephrologists, surgeons, nursing staff, anaesthetic department, operating room managers and relevant staff of their obligations as part of the ANZKX Program.



- Ensure the appropriate accreditation and credentialing of donor surgeons participating in the ANZKX Program in line with the Transplant Society of Australia and New Zealand (TSANZ) Guidelines for Hospitals to Assist in Credentialing of Transplant Surgeons in Australia and New Zealand. This includes informing the ANZKX Clinical Director and Coordinator of any surgeons new to the ANZKX Program.
- Obtain written agreement/consent from donors and recipients before enrolling them in the ANZKX Program.
- Ensure donors meet the criteria outlined in the ANZKX manual.
- Ensure data entered into the KPD section of the Transplantation Portal in OrganMatch is accurate and up to date, to the best of the participating hospital knowledge.
- Aim to confirm the scheduling of retrieval and transplant surgery within 10 days of a match being confirmed by the ANZKX Program Clinical Director.
- Scheduling of ANZKX Program live donor nephrectomies and transplantation surgery requires flexibility in access to theatre and might require booking outside of usual surgical lists.
- Aim for completion of retrieval and transplant surgeries within 100 days from the date of matching (approximately 90 days from the date the match is offered to the recipient unit).
- Surgical dates, once agreed by units involved in an exchange, should not be cancelled unless for donor or recipient clinical issues.
- Complete the perfusion and packaging of kidneys after live donor nephrectomies in accordance with the requirements in the ANZKX User Manual.
- If a participating hospital's donor surgeon is new to the ANZKX Program then the participating hospital must inform the ANZKX Clinical Director and Coordinator. Another surgeon, with experience performing live donor nephrectomies in the ANZKX Program, must also attend the operating theatre to supervise and assist in the kidney perfusion and packaging.
- Ensure ANZKX-related media requests are managed in accordance with the agreed ANZKX Media Protocol as described in the ANZKX User Manual.

Participating Hospitals agree to provide the following data and reports as requested by the ANZKX Clinical Director:

- The names of surgeons performing live donor nephrectomies at the participating hospital (Participating Hospital must ensure the relevant surgeons consent to the disclosure of their personal information to RMH).
- The total number of live donor nephrectomies performed by each surgeon each year. Participating Hospitals agree that its data and reports supplied to RMH may be incorporated into reports prepared by RMH and submitted to the OTA.

## Structure, Coordination and Oversight of the ANZKX Program

The ANZKX Program includes the following operational features: ANZKX Coordination Centre, OrganMatch, Local Tissue Typing Laboratories and Transplant Centres.

### ANZKX Coordination Centre

The ANZKX Program includes the ANZKX Coordination Centre whose responsibility is to coordinate, liaise and closely collaborate with transplant centres and tissue typing laboratories. It will maintain standard and agreed protocols and processes for:

- enrolling donors and recipients;



- ensuring consent to participate in the ANZKX Program has been obtained from donors and recipients;
- obtaining approval from State Ministers of Health for exchanges involving Australia pairs, in accordance with state legislative requirements;
- ensuring donor/recipient pairs are fully evaluated and medical/surgical assessment is complete, in line with agreed national criteria;
- safeguarding the privacy of all participants and protecting personal medical information, including genetic information;
- ensuring close and consistent collaboration with local transplant centres and tissue typing laboratories;
- coordinating transport plans and organising donor organ transport and
- ensuring uniform standards for organ packaging and transportation. Transportation will be coordinated through the ANZKX Coordination Centre and be funded through the ANZKX Program.

The ANZKX Coordination Centre comprises the following staff, funded through the ANZKX Program:

**ANZKX Clinical Director** – responsible for the overall management of the Program including:

- supervising the ANZKX Program Coordinator;
- reviewing the policies and protocols of ANZKX;
- liaising with Transplant Centres;
- liaising with the ANZKX Tissue Typing Coordinator/HLA Laboratory Director;
- liaising with RACOS and RTAC for advice and endorsement of relevant changes in policies and procedures;
- liaise with RACOS for advice regarding potential donors with complex clinical issues;
- liaising with RACOS surgical representative to consult on potential donors with equivocal renal anatomy and other surgical issues;
- liaising with and reporting to the National Renal Transplant Advisory Committee (RTAC) ANZKX Clinical Oversight Subcommittee (RACOS) regarding activity, process changes and changes to policies and procedures at quarterly intervals and;
- reporting in writing twice a year to RTAC (Australia) and the National Renal Transplant Leadership Team (NRTL, New Zealand) regarding activity, process changes and changes to policies and procedures.
- reporting in writing twice a year to the Organ and Tissue Authority (Australia) and the New Zealand Ministry of Health regarding activity, process changes and changes to policies and procedures.

**ANZKX Deputy Clinical Director** – responsible to support the Clinical Director in overall management of the program including:

- supervising the ANZKX Program Coordinator;
- reviewing the policies and protocols of ANZKX;
- liaising with Transplant Centres;
- liaising with the ANZKX Tissue Typing Coordinator/HLA Laboratory Director;
- liaising with RACOS and RTAC for advice and endorsement of relevant changes in policies and procedures;
- liaise with RACOS for advice regarding potential donors with complex clinical issues;
- liaising with RACOS surgical representative to consult on potential donors with equivocal renal anatomy and other surgical issues;



- liaising with and reporting to the National Renal Transplant Advisory Committee (RTAC) ANZKX Clinical; Oversight Subcommittee (RACOS) regarding activity, process changes and changes to policies and procedures at quarterly intervals; and
- reporting in writing twice a year to RTAC (Australia) and the National Renal Transplant Leadership Team (NRTLTL, New Zealand) regarding activity, process changes and changes to policies and procedures.
- reporting in writing twice a year to the Organ and Tissue Authority (Australia) and the New Zealand Ministry of Health regarding activity, process changes and changes to policies and procedures.

**ANZKX Program Coordinator** – responsible for:

- liaising with Local Transplant Centres to coordinate the registration of donor and recipient pairs;
- liaising with State Health Departments regarding Ministerial Approval;
- liaising with the ANZKX Tissue Typing Coordinator;
- facilitating surgical review of identified matches and identification of an appropriate date for exchange surgery;
- coordinating transport plans and surgery details of scheduled exchange surgeries with local transplant centres;
- supervising and coordinating organ transport during exchange surgeries;
- reviewing policies and protocols of ANZKX.

**ANZKX Deputy Program Coordinator** – responsible to support the ANZKX Program Coordinator including:

- liaising with local transplant centres to coordinate the registration of donor and recipient pairs;
- liaising with State Health Departments regarding Ministerial Approval;
- liaising with the ANZKX Tissue Typing Coordinator;
- facilitating surgical review of identified matches and identification of an appropriate date for exchange surgery;
- coordinating transport plans and surgery details of scheduled exchange surgeries with local transplant centres;
- supervising and coordinating organ transport during exchange surgeries;
- reviewing policies and protocols of ANZKX.

**ANZKX Tissue Typing Coordinator (ATTC)** – responsible for:

- liaising with tissue typing laboratories in various Australian states and in New Zealand to coordinate and monitor consistent blood sera and tissue typing;
- ensuring the final tissue matching quality of the transplant pairs;
- determining acceptable/unacceptable tissue matching;
- coordinating final donor/recipient cross-matching between matched pairs;
- reviewing Tissue Typing/OrganMatch policies and procedures for ANZKX;
- reporting to the Authority and ANZKX Coordination Centre on the TTL activity and issues.

**ANZKX Administrative Officer** – responsible for:

- support the ANZKX Clinical Director, Deputy Director, Program Coordinator and Deputy Program Coordinator in clerical and administrative tasks and communication;



- assist with the preparation and distribution of reports such as:
  - ANZKX Communiques
  - ANZKX Monthly Activity Updates
  - ANZKX Annual Reports
  - OTA Progress Reports (including distribution of ANZKX program activity data each month)
  - RACOS minutes
- assist with the preparation, editing and updating of ANZKX protocols, forms and pathways;
- maintain and update the ANZKX contacts list for all participating transplant units and referring hospitals;
- assist with the management of ordering and supply of equipment to all participating transplant units.

### **ANZKX HLA Laboratory Director**

This position is not an ANZKX-funded position but is sourced from within the contracted laboratory infrastructure. This position will provide high level tissue typing expertise to ANZKX for policy and program development. The ANZKX Tissue Typing Coordinator will undertake their assigned tasks in consultation with the ANZKX HLA Laboratory Director.

## **ANZKX Oversight Structure**

### **RTAC (Renal Transplant Advisory Committee) – Australia**

RTAC is the peak body providing advice regarding renal transplantation in the areas of retrieval, allocation and standards of practice. RTAC responsibilities include regular review of the interstate exchange program; oversight and review of eligibility criteria and allocation protocols for kidney transplantation; provision of advice to the OTA on specialist operational, clinical, technical or ethical advice related to the ANZKX Program.

### **National Renal Transplant Leadership Team (NRTL) – New Zealand**

NRTL is analogous to RTAC within New Zealand and provides oversight to the NZ Kidney Allocation Scheme (NZKAS), and reviews eligibility and allocation protocols for non-directed live donor and deceased donor kidneys within NZ. NRTL provides two NZ representatives to RACOS for the purposes of clinical oversight of the ANZKX. Further information regarding NZKAS is available via the link below:

[https://www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/national-renal-transplant-service/nrts-papers-and-reports#national\\_kidney\\_allocation](https://www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/national-renal-transplant-service/nrts-papers-and-reports#national_kidney_allocation)

### **ANZKX Clinical Oversight Committee (RACOS)**

- The RTAC ANZKX Clinical Oversight Subcommittee ('**RACOS**') was established to specifically manage and focus on ANZKX matters. The RACOS membership consists of the ANZKX Clinical Director, Clinical Deputy Director and Program Coordinator, nephrologists, surgeons and tissue typing scientists that have the clinical and technical expertise required to provide clinical oversight of the ANZKX Program.
- RACOS provides advice regarding clinical issues such as the suitability of medically complex donors.
- RACOS reviews ANZKX activity at meetings 3 times per year. RACOS convenes outside scheduled RTAC meetings and provides reports to RTAC meetings.
- RACOS has the ability to escalate unresolved issues to the Chair of RTAC for resolution.
- It is the responsibility of RACOS and RTAC to review events that occur within ANZKX which are deemed to be outside the protocol or accepted standards of practice or which are associated with a risk of adverse clinical outcomes and are presented to RACOS and RTAC by the ANZKX Program Clinical Director. RACOS and RTAC can request further information from the ANZKX Clinical Director and from





participating centres and has the ability to recommend outcomes including requiring modifications to centres participation or removal from the program.

## OrganMatch

OrganMatch is a clinical transplant system that facilitates matching of recipients and donors for all aspects of organ transplantation in Australia, including ANZKX, and is used solely for ANZKX in New Zealand.

Information on access to OrganMatch and its protocols is available on the OTA website here:

<https://www.donatelife.gov.au/for-healthcare-workers/organmatch>

OrganMatch's KPD section of the Transplantation Portal has been developed to provide a platform for clinicians to register donor/recipient pairs, update patient information, and receive and evaluate offers in the ANZKX program. The portal includes all clinical and immunological data on donor/recipient pairs that are registered. It enables communication between transplant centres, the Tissue Typing laboratories and the ANZKX Coordination Centre.

The ANZKX Coordination Centre is the administrator of the KPD section of the Transplantation Portal and user access is limited to nephrologists, surgeons and renal transplant coordinators at participating centres.

Transplant coordinators enter and upload donor/recipient pair information at the time of enrolment, as per the *How to Guide* located here on the OrganMatch training hub:

<https://www.donatelife.gov.au/for-healthcare-workers/organmatch/training-hub>

Transplant centres are only able to enter and view patient details from their own centre.

The ANZKX Coordination Centre is able to view all donor/recipient pairs on the platform and ensure clinical information is up-to-date and complete prior to activation.

OrganMatch is then used by the ANZKX Tissue Typing Coordinator to identify potential matches between ANZKX donor/recipient pairs.

OrganMatch software has been developed with agreed, clear and transparent algorithms to match donor and recipient pairs. All ANZKX immunological information is maintained in the OrganMatch database, with access only available to authorised OrganMatch users. Australian state and New Zealand based tissue typing laboratories provide tissue typing data for entry into OrganMatch for all pairs registered in their jurisdiction, and in accordance with the agreed Standard Operating Procedures. (See *Tissue Typing Laboratory Guidelines for the ANZKX Program*).

Once potential matches have been identified, the ANZKX Coordination Centre will contact the clinicians at the matched transplanting units to review the offers in OrganMatch. The transplanting units will then contact the ANZKX Coordination Centre following review of the match as to whether the offer is acceptable or not.

## Consent requirements and processes

ANZKX has clear and detailed protocols and processes in place regarding informed consent and registration on the ANZKX Registry. Each participating ANZKX Transplant Centre or Renal Service should:

- provide potential participants with required information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation prior to consent;
- obtain written informed consent, known as the Agreement to Participate, from each participating donor and recipient pair in accordance with agreed protocols; and
- inform donors and recipients that they may exercise their right to withdraw for any or no reason, at any time up to the commencement of surgery.

The information provided will be presented in a non-coercive way that supports individual decision-making and does not create an improper inducement to participate in ANZKX.



Important elements in optimising voluntary informed consent in this setting include:

- 1 Interview of the donor conducted apart from the recipient.
- 2 Donor assessment processes independent from the recipient team.
- 3 Separate and distinct agreement to enter ANZKX (not an assumption when found incompatible for directed donation).
- 4 The Donor Agreement to Participate also includes mandatory completion of the Donor Declaration and the requirement for Nucleic Acid Testing (NAT) prior to surgery.
- 5 Detailed explanation of all the existing conditions of participation in the ANZKX Program, as outlined in the Agreement to Participate documents and the ANZKX Protocol.
- 6 Discussion regarding the possibility of being a bridge donor.
- 7 Mandatory pre-donation counselling with an option of post-donation counselling as required.

The informed consent process will include reference to the human biological materials and data to be collected and the health and other records to be accessed, their intended uses, storage and duration of storage, transfer and disposal procedures. In this regard, each transplant centre will follow its own specific ethical guidelines.

The informed consent process must ensure that participants understand the requirement for, and agree to, disclosure of necessary identifying information to enable application for Ministerial approval.

Where an ANZKX policy, protocol or procedure is significantly modified, the ANZKX Coordination Centre will, where feasible, ensure that a new consent is obtained from participants on the register who are not yet scheduled for pairing.

ANZKX will ensure that policy addresses appropriate contingency plans in the rare event of an ‘orphaned recipient’ where transplantation could not proceed as planned. The conditions whereby an “orphaned kidney” and an “orphaned recipient” result, and the planned outcomes for these contingencies, must be clearly explained to ANZKX participants to ensure consent is fully informed.

## Protocol for orphaned kidneys and recipients

### Definitions

**Orphaned kidney:** Refers to a kidney removed from an ANZKX donor that cannot be transplanted into the matched recipient.

**Orphaned recipient:** Refers to an ANZKX recipient whose co-registered donor has donated, but who has been unable to receive a kidney from the matched donor

The protocol for orphaned kidneys and orphaned recipients was developed by the National Paired Kidney Exchange Program Advisory Group and has been revised by RACOS and RTAC (Australia).

In New Zealand the NRTLTL oversees the protocol for handling orphaned recipients/kidneys.

### Orphaned Kidney

A recipient may acutely deteriorate during induction or during their operation such that the procedure needs to be abandoned. If the donor has already had their kidney removed, this results in an ‘orphaned kidney’. Prior to consenting to enter the ANZKX program donors are advised that in this rare circumstance, their kidney would be allocated to someone suitable on the transplant waiting list. It is for this reason that donor blood samples are taken at anaesthetic induction and transported with the kidney.



Once the originally intended recipient has recovered and is suitable for transplantation, his/her incompatible co-registered donor will already have donated a kidney in the ANZKX Program. This recipient will receive priority for a suitable kidney from the deceased donor organ pool (refer to 'orphan recipient' below).

## Process for determination and allocation of an orphaned kidney

### Recipient Centre

Must immediately notify the ANZKX Coordination Centre if the recipient has become acutely ill and is unable to undergo or continue with transplant surgery.

### Steps for allocation of an orphan kidney

The ANZKX Coordination Centre will determine current location of orphaned kidney and determine which country it will be allocated in. Typically, if it has already departed on a trans-Tasman flight it will be allocated in the country it is going to arrive in; otherwise it will be allocated in the country it is in at the time it is determined to be orphaned.

#### If an orphaned kidney is to be allocated in Australia:

- Depending on the logistics, an allocation to a highly sensitized recipient on the deceased donor waiting list (Level 1-3 on the National Allocation formula) should be sought. A decision regarding whether further transport of the kidney is possible for such an allocation will be made by the ANZKX Coordination Centre although advice from RACOS can be requested if required.
- If this is not possible or there is no recipient matched at level 1-3 on the National Allocation formula then:
  - If the kidney is in transit, the kidney will be allocated to a recipient on the transplant waiting list in the state of destination.
  - If the kidney is still in the state of origin, it will be allocated to a transplant waiting list recipient within this state.
- The ANZKX Coordination Centre will alert the ANZKX Tissue Typing Coordinator to perform urgent allocation to the transplant waiting list / virtual crossmatch to identify a suitable recipient.
- The ANZKX Tissue Typing Coordinator will notify the ANZKX Coordination Centre about the identified potential match and the transplanting centre under which the identified recipient is listed.
- The ANZKX Coordination Centre will contact recipient's transplant centre to alert of the probable allocation. The de-identified live donor report will be made available to the recipient's team in OrganMatch.
- The ANZKX Tissue Typing Coordinator will alert the relevant Tissue Typing Laboratory to prepare for an urgent cross-match test.
- The Tissue Typing laboratory performing the crossmatch will send a report to the recipient's centre, with copy to the ANZKX Coordination Centre and ANZKX Tissue Typing Coordinator and ensure the waiting list recipient's centre has been duly informed.
- The ANZKX Coordination Centre will report the critical incident to RACOS and monitor outcomes.
- The ANZKX Coordination Centre will facilitate communication of the resultant issues and outcomes between donor and recipient centres as required.

#### If an orphan kidney is to be allocated in New Zealand:

ANZKX will notify the Medical Director of the NZKAS, who will register the donor's information in the NZKAS and run the allocation as per the NZKAS.



## Orphaned recipient

There may be multiple reasons for this eventuality, some of which are:

- donor nephrectomy could not be completed due to donor becoming acutely ill during surgery;
- kidney was lost in transit or the wrong kidney was delivered;
- kidney received by transplanting hospital was damaged during transport or packaging and is found to be inappropriate;
- kidney received by transplanting hospital was unable to be transplanted due to surgical issues;
- recipient is acutely unwell and cannot undergo transplant surgery (see 'orphan kidney').

The outcome is that the intended recipient cannot receive a kidney, and is therefore an 'orphaned recipient'. The recipient's co-registered donor has already donated his/her kidney and thus the recipient no longer has recourse to an exchange.

Each country will be responsible for any orphaned recipients enrolled in their country, irrespective of the cause of the recipient becoming orphaned.

In Australia, the 'orphaned recipient' will receive priority listing on the transplant waiting list (Level 3-4 interstate exchange) for a suitable kidney from the national deceased donor organ pool. In the case of a very highly sensitised recipient (very high calculated panel reactive antibody level) who is likely to be difficult to match, the amount of priority can be altered depending on the advice of RTAC.

Pre-emptive recipients are not listed in OrganMatch, as activation on the deceased donor waitlist starts with the first day on dialysis. In these cases, exception will be made after notification and approval by RTAC that the pre-emptive recipient can be listed for priority allocation on the deceased donor waiting list.

**If a kidney is transplanted and kidney reperfusion has been established, the recipient will not be considered an orphan recipient, even if the kidney never functioned.**

**However, if the transplant surgeon finds that the kidney is visibly damaged prior to surgery and proceeds but early graft loss occurs, the recipient would still be eligible to be prioritized according to the Orphaned Recipient protocol if approved by RTAC. In this situation the transplant surgeon needs to have informed the ANZKX Coordination Centre prior to proceeding with surgery.**

**In New Zealand, NRTLTL is responsible for determining that the recipient has been 'orphaned'. Where that is the case, they receive prioritisation on the deceased donor waiting list, according to the NZKAS algorithm.**

**In cases where there is clinical uncertainty regarding potential eligibility as an orphan recipient urgent advice can be sought from RACOS or RTAC members.**

**Process for determination of an orphaned recipient and subsequent allocation of a kidney:**

### Donor Centre

Must immediately notify the ANZKX Coordination Centre if:

- the donor becomes acutely ill during surgery;
- there are unforeseen surgical issues which result in an aborted nephrectomy;
- the removed kidney is visibly damaged at the time of removal or during packaging.

### Recipient Centre

Must immediately notify the ANZKX Coordination Centre if:

- the kidney has not reached the hospital by the expected delivery time;

- the kidney delivered is not for the intended recipient;
- the transplant surgeon determines that the kidney received is not suitable for transplant (e.g. kidney is damaged and non-transplantable);
- the transplant surgeon determines that the kidney received is visibly damaged but potentially transplantable; **(in this situation the surgeon should inform the ANZKX Coordination Centre prior to surgery).**
- the recipient becomes acutely ill during surgery, and the kidney can't be transplanted in the intended recipient on that occasion.

### ANZKX Coordination Centre

After receiving notification from either the Donor or Recipient Centre, the ANZKX Coordination Centre will:

- immediately advise the recipient centre when an aborted donor nephrectomy has been reported and a kidney will not be forthcoming;
- work with the courier company to locate a delayed/lost kidney;
- report the critical incident to the OTA/RACOS and monitor outcomes;
- facilitate communication of the resultant issues and outcomes between donor and recipient centres.

**The *Information for Donors and Recipients* form expressly addresses “orphan kidney” and “orphan recipient” eventualities, which must be discussed during the consent process, and clearly understood by the potential donor and recipient pairs.**

## Protocol for non-directed altruistic donors

Non-directed altruistic donors (NDAD) can be registered in ANZKX according to the preferences and protocols of the referring clinicians and the donor. NDADs entered into paired exchange programs can lead to the creation of long recipient chains and increase the chance of transplanting highly sensitized individuals.

## ANZKX Documents and Confidentiality

The ANZKX Program requires the maintenance of confidentiality of all donor/recipient details, and the preservation of anonymity between exchange pairs. Therefore, filing of certain ANZKX documents must be carefully considered in terms of access of information. It is highly recommended that each centre has a designated ANZKX confidential filing system, accessible to designated authorised personnel only.

Specific guidelines as follows:

All standard information for donor/recipient pairs that does not identify an exchange donor and/or recipient is filed as per current hospital protocol, i.e. in individual medical record.

These documents are:

- 1 ANZKX Agreement to Participate for Donors and Recipients
- 2 ANZKX Donor Declaration Form
- 3 ANZKX Ministerial Approval Form (Australia only)

Specific ANZKX documents which identify participating pairs in an exchange, and details on donor/recipient information from other centres (e.g. when an exchange has occurred) must not be filed in the patients' medical record.

These documents are:

- 1 ANZKX Surgical Checklist Form



- 2 ANZKX Living Kidney Donation Report
- 3 Exchange Donor CTA report and images
- 4 Match Report from OrganMatch

## ANZDATA and post-transplant reporting

Standard reporting using the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) Living Kidney Donor Registry forms and AUS. & N.Z. Dialysis & Transplant Survey sheet remains the same, with the following conditions:

### 1 Living Kidney Donor Registry – Pre-Donation Data form

- Complete all data as required on form, leaving the **Recipient Details** section blank.
- Enter code #402 (Non-directed kidney exchange) or #403 (Directed kidney exchange) in the **Donor Relationship to Recipient** sections and specify as **PKE**.

DONOR RELATIONSHIP TO RECIPIENT						
Code	Description (refer to Source of Donor Kidney list on back of the form)					
RECIPIENT DETAILS						
ANZDATA NUMBER	RECIPIENT SURNAME	RECIPIENT GIVEN NAME	DATE OF BIRTH			
			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			

*The ANZKX Coordination Centre will provide recipient details to ANZDATA, upon advisement of receipt of ANZDATA form.*

### 2 Living Kidney Donor Registry – Operative Data form

- Use the ANZKX Living Kidney Donation Report form and your centres operation report to complete the information required.
- The **Recipient ANZDATA Number** will not be available hence leave blank.

DONOR DETAILS									
LIVING DONOR NUMBER	DONOR SURNAME	DONOR GIVEN NAME			DATE OF BIRTH				
					<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>				
DATE OF DONATION	Donor Facility	Donor MRN	Surgeon	RECIPIENT ANZDATA NUMBER	Transplant Facility				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>									

- The **Donor Facility** – indicates the place of nephrectomy.
- The **Transplant Facility** – indicates the place of recipient transplant surgery. This is in the majority of cases at a centre other than the Donor Facility and can also potentially be in another State.



**3 Real Time Web Data Entry**

Notifying a change in treatment course i.e. transplantation, requires the same donor data as specified above. Please enter the **Donor Source** code as #402 (Non-directed kidney exchange) or #403 (Directed kidney exchange).

**4 AUS. & N.Z. Dialysis & Transplant Survey sheet (for recipients)**

In the **Current Graft** section under **Donor Details** please enter the **Source of Donor Kidney** code as either #402 (Non-directed kidney exchange) or #403 (Directed kidney exchange). Other operative data required may be obtained as previously detailed in Point 2 above.

CURRENT GRAFT (IN THE EVENT OF BOTH GRAFT FAILURE AND RE-TRANSPLANT IN THIS SURVEY - USE A NEW FORM)											
GRAFT NUMBER		DATE OF THIS TRANSPLANT			REFERRING HOSPITAL	DONOR HOSPITAL	TRANSPLANT HOSPITAL	RECIPIENT ANTIBODY (Status at Graft)		ANASTOMOSIS SITE Complete a Surgical Form (Form SU)	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	L = Left R = Right
DONOR DETAILS		TOTAL ISCHAEMIA		IMMEDIATE FUNCTION	DISEASE IN GRAFT	DATE FIRST PROVEN (eg. Graft biopsy)		GRAFT FAILURE CAUSE (Record from list)		Serum Creatinine at Graft Failure	
SOURCE	AGE	SEX	<input type="text"/>	(Hours)	<input type="text"/>	(See list)	<input type="text"/>	<input type="text"/>	<input type="text"/>	OTHER -	<input type="text"/>

These guidelines have been developed in collaboration with ANZDATA.



## Part 2: Process for the ANZKX Program

### Pre-enrolment process, consent and Ministerial Approval

#### 1. Initial discussion with incompatible donor / recipient pair

<b>Who</b>	Local Renal Specialist
<b>Where</b>	Local Renal Unit
<b>What</b>	<ul style="list-style-type: none"> <li>• Provide the donor and recipient with information about ANZKX, including the <i>Frequently Asked Questions</i> form and <i>Information for Donors and Recipients</i> form.</li> <li>• If donor/recipient wish to consider ANZKX go to 2.</li> </ul>

#### 2. Provide full information about ANZKX and other options of incompatible living kidney donation

<b>Who</b>	Local Transplant Team Nephrologist
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Provide the donor and recipient with full information about all the living donor options between an incompatible donor and recipient available to them, and conditions of participation in ANZKX.</li> <li>• If donor/recipient agree to ANZKX go to 3.</li> </ul>

#### 3. Agreement to Participate in ANZKX & Ministerial Approval

The process for seeking donor and recipient agreement to participate and ministerial approval differs in each jurisdiction based on legal requirements (See Ministerial Approval process for full details).

**The Agreement to Participate and Ministerial Approval by state is outlined as such:**

All donors and recipients must sign an Agreement to Participate in the ANZKX Program. (Donors are also required to complete the *Donor Declaration Form* in the presence of the interviewer (physician or nurse). The *Donor Declaration Form* is not submitted with *Ministerial Approval Form* but a copy is required by the ANZKX Coordination Centre.

If donor/recipient is a resident of ACT, NSW, TAS or WA, Agreement to Participate must be obtained prior to seeking Ministerial Approval. **Go to 3.1 then 3.2.**

ACT participants require Ministerial Approval from ACT and NSW Ministry of Health (MoH).

TAS participants only require Ministerial Approval if Agreements to Participate are signed in Tasmania.

If donor/recipient is a resident of SA or NT, Ministerial Approval must be gained prior to obtaining Agreements to Participate. **Go to 3.2 then 3.1.**

NT participants require Ministerial Approval from NT and SA (MoH), even if the Agreements to Participate have been signed in SA.

If donor/recipient is a resident of QLD or VIC, Ministerial Approval is not required. Go to 3.1. However, if a donor or recipient co-registered with a QLD/VIC participant resides in NSW, WA, or SA and will have surgery in the home State, Ministerial Approval applicable to that State will be required.



If donor/recipient is a resident of New Zealand then Ministerial Approval is not required.

### 3.1. Agreement to Participate

<b>Who</b>	Local Transplant Team Nephrologist
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>Obtain signed copies of the <i>Recipient Agreement to Participate</i>, <i>Donor Agreement to Participate</i> and <i>Donor Declaration</i> forms for the donor and recipient pair about to participate in the ANZKX Program.</li> <li>Submit the signed <i>Recipient Agreement to Participate</i>, <i>Donor Agreement to Participate</i> and <i>Donor Declaration</i> forms to the ANZKX Coordination Centre via the Transplantation Portal in OrganMatch.</li> </ul>

### 3.2. Ministerial Approval to Participate (not for QLD/VIC)

<b>Who</b>	Local Transplant Team Nephrologist
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>Complete Section 1 of the <i>Ministerial Approval Form</i>.</li> <li>Submit the <i>Ministerial Approval Form</i> to the ANZKX Program Coordinator via email.</li> </ul>
<b>Timing</b>	The Ministerial Approval process should take between 1-2 weeks.

**Please note the following for the Ministerial Approval Process to be expedited:**

- In SA/NT, a scanned copy of the Ministerial Approval document is acceptable for submission.
- In NSW/ACT/TAS/WA scanned copies of Agreements to Participate and Ministerial Approval documents are acceptable for submission.
- Scanned copies must be clearly legible or they may not be accepted. It is therefore recommended that a dark pen and block letters (other than signatures) are used when completing documents.

## Enrolment and Medical Evaluation

### 4. Medical Evaluation

Prior to activating a donor/recipient pair in the ANZKX registry both the donor and the recipient must already be determined to be medically suitable for the transplantation procedure. Pre-emptive recipients require medical suitability clearance by the Local Transplant Centre and the submission of HLA serum samples to Tissue Typing laboratories as advised by the local TT officer.

<b>Who</b>	Local Transplant Team Nephrologist
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>Determine donor (and recipient) medical suitability for the transplantation procedure according to Protocol 3: Living Donor Evaluation Guidelines.</li> <li>Organise donor CT angiogram as per Protocol 8: Recommended Donor CTA Protocol, Reconstruction &amp; Reporting Standard.</li> </ul>

- |  |   |
|--|---|
|  | <ul style="list-style-type: none"> <li>Assess donor latent TB risk as per Protocol 10: Latent Tuberculosis Infection Pathway for Donors.</li> </ul> |
|--|---|

## 5. Create KPD enrolment for donor / recipient pairs in the OrganMatch Transplantation Portal

Registration of donor/recipient pairs may commence at any time during the medical assessment process, but the evaluation must be completed and the donor/recipient pair deemed medically and surgically suitable for transplantation, prior to activation in the OrganMatch Transplantation Portal. A CD-ROM of the donor's CT angiogram, and the CT report, must be sent to the ANZKX Coordination Centre as soon as available (this is in addition to uploading the report into OrganMatch).

**The CD-ROM, USB or electronic image transfer of donor CTA and CTA report must not be de-identified.**

**Where an anatomical anomaly has been identified on the CT report (e.g. liver or kidney cyst, or an unidentified lesion) and further imaging has been recommended, please provide the relevant report in addition to the CT report.**

<b>Who</b>	Local Transplant Team Nephrologist/Renal Transplant Coordinator
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>Enter clinical information required for KPD enrolment on donors and recipients into the OrganMatch Transplantation Portal.</li> <li>Forward a CD-ROM, USB (or electronic image transfer) of the donor's CT angiogram, plus CT report, to the ANZKX Coordination Centre.</li> </ul>

## 6. Immunology data entered into OrganMatch

Paired kidney exchange specific tissue typing requirements are mandatory to enrol donor/recipient pairs in the ANZKX Program.

For entry onto the KPD pathway:

**Donors** must have an authorised HLA typing at **4-digit level** recorded into OrganMatch for each of the following mandatory HLA loci:

**HLA-A\*, HLA-B\*, HLA-Cw\*, HLA-DRB1\*, HLA-DQB1\*, HLA-DQA1\*, HLA-DPB1\* and HLA-DRB3/4/5\*.**

**Sensitised recipients** must have an authorised Class I and Class II HLA antibodies by solid phase single antigen bead assays (Luminex) at **4-digit level** recorded into the OrganMatch. DSA with MFI>2000 (One Lambda) or >1500 (Immucor) excludes from matching.

ANZKX Tissue Typing requests should be submitted to the relevant Australian state or New Zealand tissue typing laboratory with these specifications, and noting that the request is specific to the ANZKX Program (sample request forms are included in the Tissue Typing Guidelines).

<b>Who</b>	Local Tissue Typing Officer
<b>Where</b>	Australian State & New Zealand Tissue Typing Laboratories
<b>What</b>	<ul style="list-style-type: none"> <li>Ensure donor/recipient immunology data (containing donor HLA type and recipient HLA type, HLA antibody screening and unacceptable antigen profile) have been entered into OrganMatch.</li> </ul>

## 7. Confirmation of donor and recipient pair information

In addition to the standard ANZKX Donor criteria, all donors must have an identified Blood Group result uploaded onto OrganMatch. **Blood Group A donors are also required to be subtyped as this is important information for any potential Blood Group incompatible transplant.**

**CT images are routinely reviewed by a Radiologist at the Royal Melbourne Hospital for extra-renal pathology. Further imaging or other testing may be requested if an abnormality is identified upon review.**

<b>Who</b>	ANZKX Program Coordinator
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<p>The ANZKX Coordination Centre will confirm that the referring transplant centre has fully evaluated the submitted donor/recipient pairs ensuring that:</p> <ul style="list-style-type: none"> <li>• Donor medical work-up is complete;</li> <li>• The donor/recipient information is complete, including:</li> <li>• CD-ROM, USB (or electronic image transfer) and report of the donor CT angiogram have been received; and any extra imaging or reports as requested after review by RMH radiology.</li> <li>• Donor/recipient pair immunology information has been completed.</li> <li>• If medical and immunology evaluation are complete, <b>go to 8.</b></li> </ul>

## Matching of pairs

### 8. Verification of active pairs

<b>Who</b>	ANZKX Program Coordinator
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<p>ANZKX Program Coordinator to verify with Local Transplant Centres approximately monthly that:</p> <ul style="list-style-type: none"> <li>• All active registered donor-recipient pairs are suitable for matching.</li> <li>• Acceptance of ABOi and Hepatitis B core positive donors as registered in OrganMatch is confirmed in accordance with recipient informed consent.</li> <li>• Blood group A donors have been subtyped and the subtype has been entered into OrganMatch.</li> <li>• Donor blood group result (identified formal NATA accredited laboratory report) has been uploaded onto OrganMatch.</li> </ul>

### 9. Matching

<b>Who</b>	ANZKX Tissue Typing Coordinator (ATTC)
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• The ATTC will perform matching continuously throughout the year.</li> </ul>

	<ul style="list-style-type: none"> <li>• A report of matched donor/recipient pairs is sent to the ANZKX Coordination Centre.</li> <li>• Recipients who have not been matched remain active on the transplant waiting list.</li> <li>• Recipients who have been matched to a suitable donor will be placed on-hold on the transplant waiting list.</li> <li>• They will be reactivated on the transplant waiting list if the chain breaks down.</li> </ul>
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## 10. Review of matched pairs by ANZKX

<b>Who</b>	ANZKX Clinical Director, ANZKX Program Coordinator, ANZKX Tissue Typing Coordinator, HLA Laboratory Director, Local TT Officers
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Review matched donor-recipient pairs.</li> <li>• Transplant centres may be contacted with potential match information as a preliminary enquiry towards acceptance/rejection of proposed match.</li> </ul>

## 11. Transplant teams notified of matched pairs

<b>Who</b>	ANZKX Program Director/Coordinator	ANZKX Tissue Typing Coordinator
<b>Where</b>	ANZKX Coordination Centre/Local Transplant Centre	All participating Australian state tissue typing laboratories and NZ tissue typing laboratories
<b>What</b>	<p>ANZKX Program Director/Coordinator:</p> <ul style="list-style-type: none"> <li>• Notify transplant teams and Australian State/NZ TTL's of identified matched pairs.</li> </ul> <p>Centres are directed to view the match event in OrganMatch:</p> <ul style="list-style-type: none"> <li>• Match pair review with details of immunological matching and donor specific antibodies.</li> <li>• Other donor information.</li> <li>• Facilitates donor specific ABOi titre if required.</li> <li>• Local Transplant Centre</li> <li>• Book XM within 5 days of notification.</li> <li>• Recall matched donors to present to Transplant Centre for cross-matching.</li> <li>• Repeat serology for HIV/HBV/HCV and CMV/EBV.</li> <li>• Repeat <i>Donor Declaration Form</i>.</li> </ul>	<p>ANZKX Tissue Typing Coordinator:</p> <ul style="list-style-type: none"> <li>• Coordinates cross matching with Australian state and NZ tissue typing laboratories to identify potential compatible pairs.</li> <li>• Australian and New Zealand tissue typing laboratories:</li> <li>• Prioritise ANZKX cross-matching. Cross matches are performed within 2 weeks.</li> </ul>

## 12. Review of cross matches

<b>Who</b>	ANZKX Clinical Director, ANZKX Program Coordinator, ANZKX Tissue Typing Coordinator, Local Australian State and New Zealand TTL's
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Review crossmatch and flow cytometric crossmatch results.</li> <li>• Approve acceptable exchanges following review of crossmatch results.</li> <li>• Appropriately de-identified cross match reports will be made available via OrganMatch.</li> <li>• Notify state laboratories to re-activate recipients with positive cross-match on the transplant waiting list.</li> </ul>

## 13. Surgical review

A review of the surgical suitability of the proposed exchange will be required by donor and recipient liaison surgeons at the respective transplant centres by way of the *Surgical Checklist* form and reviewing donor CTA images.

As the donor is identified in this instance, the signatories of this report guarantee to maintain anonymity of the donor, and will not disclose any donor information with other members of the transplant teams or recipient.

Surgical review will take place in a 5-step process:

- 1 ANZKX Program Coordinator completes donor/recipient information and forwards the *Surgical Checklist* form to the donor surgeon. The donor CTA CD (imaging) is also sent to recipient centre at the same time.
- 2 Donor Surgeon notes preference for kidney to be removed, type of perfusion solution/heparinisation, signs and returns form to ANZKX Coordination Centre.
- 3 ANZKX Program Coordinator then forwards the signed *Surgical Checklist* form to the Recipient Surgeon.
- 4 Recipient Surgeon reviews donor kidney anatomy, and decides on acceptability of the proposed organ. The *Surgical Checklist* form is signed again and returned to the ANZKX Coordination Centre. Direct communication between the donor and recipient surgeon might also be required during this step.
- 5 The ANZKX Coordination Centre distributes the signed *Surgical Checklist* forms to all involved centres as confirmation of the exchange, two weeks prior to the agreed surgical date.

**Please note:** At this point centres should always double check that the side of nephrectomy agreed on in the *Surgical Checklist* matches the local surgical plan.

If an exchange has been determined as not acceptable by the recipient surgeon the checklist must be signed accordingly and returned immediately to the ANZKX Coordination Centre. The ANZKX Coordination Centre will take appropriate action in conjunction with the involved transplant centres.

<b>Who</b>	ANZKX Program Director/Coordinator	Recipient and Donor Liaison Surgeons
<b>Where</b>	ANZKX Coordination Centre / Local Transplant Centre	Local Transplant Centres
<b>What</b>	ANZKX Program Coordinator:	Recipient & Donor Liaison Surgeons:

<ul style="list-style-type: none"> <li>• Sends CD-ROM or electronically transfers donor imaging to recipient liaison surgeon.</li> <li>• Sends <i>Surgical Checklist</i> forms to donor and recipient liaison surgeons.</li> <li>• Action Surgical Cross-Match result as required.</li> </ul>	<ul style="list-style-type: none"> <li>• Complete and send <i>Surgical Checklist</i> form to the ANZKX Coordination Centre.</li> <li>• Advise the ANZKX Coordination Centre immediately if exchange not acceptable.</li> </ul>
If proposed matches are acceptable, <b>go to 15.</b>	

#### 14. Negotiation of transplant dates.

Concurrent with surgical review and immunological crossmatches, negotiation of dates for surgery will commence. Priority is given to units with multiple pairs within an exchange.

The goal of the ANZKX Program is to aim for surgery 4-6 weeks from the time of matching.

**Please note:** That in transplant centres where donor nephrectomies are performed by Urologists (not usually involved in deceased donor transplants) it is understood that experience with packaging of the donor kidney will be limited. Therefore the consensus amongst donor and recipient surgeons is that in these instances a transplant recipient surgeon will be present in theatre to assist with this process.

#### 15. Logistics for Exchange

<b>Who</b>	ANZKX Program Coordinator
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Confirm date of surgery acceptable to Local Transplant Centres and donor/recipient pairs.</li> <li>• Inform the relevant Australian and New Zealand Tissue Typing Officers regarding the date of transplants.</li> <li>• Identify responsible person at each site that will oversee coordination of surgical timelines; and</li> <li>• Send a preliminary transport itinerary to transplant teams to assist with operative scheduling.</li> </ul>

### Before surgery

#### 16. Transport and Packaging resources available

The ANZKX Coordination Centre will ensure that ANZKX transport packs consisting of container and packaging materials (ANZKX Transport Pack) are distributed to all transplant centres.

These packs are to be stored in a specially designated safe and secure area in the renal transplant department. These supplies will be replenished as necessary by the ANZKX Coordination Centre upon request from the transplant centre.

<b>Who</b>	ANZKX Program Coordinator and Local Transplant Team
<b>Where</b>	ANZKX Coordination Centre and Local Transplant Centre

<b>What</b>	<ul style="list-style-type: none"> <li>• ANZKX Program Coordinator to send ANZKX transport pack.</li> <li>• The Local Transplant Centre to ensure ANZKX transport pack is available prior to a potential exchange and check that surgical schedules are in place.</li> </ul>
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## 17. Recipient Luminex Single Antigen Bead (SAB) testing

There may be a delay of several weeks between initial cross-match and surgery, increasing the risk of an adverse immunological outcome. Should transplants be delayed for any reason, **serum from within 4 weeks** of the transplant date will need to be retested by Luminex SAB.

<b>Who</b>	ANZKX Program Coordinator, Local Transplant Centre, ATTC, Local TT Lab
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<p>At least 4 weeks prior to surgery, ANZKX Program Coordinator will:</p> <ul style="list-style-type: none"> <li>• Remind transplant centres of necessity for collection of HLA serum.</li> </ul> <p>The ANZKX Tissue Typing Coordinator/Local TT lab will:</p> <ul style="list-style-type: none"> <li>• Review current SAB analysis.</li> <li>• Ascertain whether a further crossmatch is required.</li> </ul>

## 18. Consent for surgery, Donor Nucleic Acid Testing and COVID-19 testing

<b>Who</b>	Local Transplant Centre/ANZKX Coordination Centre
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Obtain consent for surgery from donor and recipient as per hospital policy. The side of planned nephrectomy should be the same as documented on the <i>ANZKX Surgical Checklist</i> form.</li> <li>• Organise collection of donor NAT samples at required pre-surgery interval. This test should be done at (or as close to) Day -9 prior to the day of surgery and should be available at least 5 days prior to surgery.</li> <li>• Organise COVID-19 testing as per the <i>ANZKX Coronavirus Disease 2019 (COVID-19) Testing</i> protocol.</li> <li>• Send result to ANZKX Coordination Centre as soon as available.</li> <li>• The ANZKX Coordination Centre will forward de-identified NAT result to recipient centre.</li> </ul> <p>If NAT or COVID-19 results are negative, <b>go to 19</b></p> <p>If NAT or COVID-19 results are positive, <b>surgeries will be deferred</b></p>

## 19. Confirm Day of Exchange details

The ANZKX Program Coordinator will confirm all logistical details with local transplant centres and ensure the ANZKX Organ Transport Itinerary has been distributed accordingly.

<b>Who</b>	ANZKX Program Coordinator
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<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<p><u>Approximately one week prior to surgery</u> ANZKX Program Coordinator confirms:</p> <ul style="list-style-type: none"> <li>• ANZKX Transport Packs have been received by each centre.</li> <li>• Anaesthetic start times and anticipated pick-up times for organs.</li> <li>• Donor Blood request forms for “PKE store cells” and Living Kidney Donation reports have been sent to centres.</li> <li>• Name of recipient transplant surgeon who will be present in theatre to assist with packaging (as applicable).</li> <li>• Flight itineraries for organs (as applicable).</li> <li>• Transport Plan, NECZ numbers &amp; Consignment Notes for Organ Transport have been received by centres.</li> <li>• Hospital pickup and delivery points and designated contacts at each hospital; and</li> <li>• Back-up itinerary and emergency contact details.</li> </ul>

## 20. Planning for internal exchanges

There is a greater risk of a kidney being transplanted into the wrong recipient when a hospital has more than one donor or recipient having their surgery on the same day, particularly when one or more kidneys remain within the same centre. When this is the case, the transplant team should meet prior to the day of surgery and ensure they have a plan for how the kidney staying within their centre will be packaged, labelled and stored prior to implantation. This should include the use of the *Living Kidney Donation Report* which should always stay with the kidney and be cross checked prior to implantation. This plan should be documented and communicated to all staff involved in the exchange, including theatre staff.

## 21. One day prior to surgery

Cross-checking of kidneys is an essential process to ensure the correct donor kidney is removed and transplanted into the matched recipient. To facilitate this, de-identified donor and recipient cross-match reports, donor NAT, ABO and CMV/EBV results are provided by the ANZKX Coordination Centre. **Donor NAT, ABO, & CMV/EBV documents must accompany the donor kidney, in addition to the Living Kidney Donation report.** The 3 main identifiers used for all de-identified documents are:

- 1 OrganMatch Identification Numbers
- 2 Date of Birth
- 3 Blood Group

<b>Who</b>	ANZKX Program Coordinator
<b>Where</b>	ANZKX Coordination Centre
<b>What</b>	<ul style="list-style-type: none"> <li>• Verify that all items in step 20 are confirmed; and</li> <li>• When non-simultaneous donor surgical start times are planned, units <u>must review</u> the donor-recipient pairs the day prior to surgery to ensure they are fit for surgery (not affected by acute illness, consent not withdrawn). In this setting it is preferable that pairs are admitted the day prior to surgery.</li> </ul>



	<ul style="list-style-type: none"> <li>Ensure de-identified copies of donor NAT, ABO &amp; CMV/EBV documents are available at the donor centre.</li> </ul>
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## Surgery and post-surgery

### 22. Day of surgery

<b>Who</b>	Local Transplant Team
<b>Where</b>	Local Transplant Centre
<b>What</b>	<ul style="list-style-type: none"> <li>Confirm <u>in separate consultations</u> donor and recipients medical and emotional suitability to participate.</li> <li>Immediately notify the ANZKX Program Coordinator and other Local Transplant Centre if donor and/or recipient withdraw.</li> <li>Notify the ANZKX Program Coordinator immediately of any last minute issue regarding consent, packaging, transport and surgery.</li> <li>For Donor Surgery, ensure that section 1 and 2 of the <i>ANZKX Living Kidney Donation Report</i> is completed appropriately and accompanies the kidney, along with the donor blood samples and de-identified NAT, ABO and CMV/EBV results.</li> <li>For Recipient Surgery, ensure the kidney received is cross-checked and correct for the recipient prior to implantation.</li> <li>In the event of an internal exchange, the hospital's plan for kidney packaging, labelling and storage prior to implantation should be followed, and the retrieved kidney checked against the <i>ANZKX Living Kidney Donation Report</i> prior to implantation.</li> </ul>

### 23. After transplantation

<b>Who</b>	Recipient Surgical Team/ANZKX Program Coordinator
<b>Where</b>	Recipient Hospital/ANZKX Coordination Centre
<b>What</b>	<p>Recipient Surgical Team:</p> <ul style="list-style-type: none"> <li>Complete section 3 of the <i>ANZKX Living Kidney Donation Report</i> and forward to ANZKX Program Coordinator within two working days of procedure.</li> </ul> <p>ANZKX Program Coordinator:</p> <ul style="list-style-type: none"> <li>Feedback any issues to transplant centres and Organ and Tissue Authority.</li> </ul>

### 24. Post-Transplant Notifications

<b>Who</b>	ANZKX Program Coordinator/Local Transplant Team
<b>Where</b>	ANZKX Coordination Centre/Local Transplant Centre

<p><b>What</b></p>	<p>ANZKX Program Coordinator:</p> <ul style="list-style-type: none"> <li>• Completes OrganMatch renal transplant notification forms and sends to ANZKX Tissue Typing Coordinator (for distribution to relevant Australian states and New Zealand centres) and ANZDATA.</li> <li>• Requests feedback of any issues.</li> <li>• Completed LKD reports are forwarded to the ANZKX Surgical Liaison,</li> </ul> <p>Local Transplant Centre:</p> <ul style="list-style-type: none"> <li>• Completes ANZDATA Living Donor Forms.</li> <li>• Provides post-transplant information as requested by ANZKX Coordination Centre.</li> <li>• Completes the <i>ANZKX Post Transplant Follow Up Form</i> 1 month post-surgery.</li> </ul>
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VERSION CONTROL			
Version	Date	Author	Comments
V 1.0	July 2019	ANZKX Team	AKX program transitioned to ANZKX.
V 2.0	Feb 2021	ANZKX Team	Match run structure changed to continuous matching.
V 3.0	Nov 2021	ANZKX Team	MMEEx transition to OrganMatch and added text regarding donors to repeat donor declaration at time of offer.
V 4.0	Apr 2022	ANZKX Team	<ol style="list-style-type: none"> <li>Added in additional details regarding internal exchanges with the addition of section 20 and changes to section 22 in <b>Part 2: Process for the ANZKX Program.</b></li> <li>Updated external web links in <b>Part 1: General Principles and Structure of the ANZKX Program.</b></li> </ol>
V 5.0	May 2023	ANZKX Team	Addition of Bridge Donor information.

