Australian and New Zealand Paired Kidney Exchange Program

Protocol 1: ANZKX Protocol

Version 5 February 2021





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
New South Wales	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
Queensland	Princess Alexandra Hospital Mater Children's Hospital	Princess Alexandra Hospital
South Australia	Royal Adelaide Hospital The Women's and Children's Hospital	Royal Adelaide Hospital
Victoria	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
Western Australia	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 ANZKX will aim for simultaneous anaesthetic induction time (AIT) for donor operations when feasible. Chains involving an exchange between Australia and New Zealand are more likely to have non-simultaneous donor AIT to allow for transport logistics and to limit the duration of kidney cold ischaemic time. This will be decided on a case by case basis.
- 6 For optimal operation, ANZKX will rely upon centralised coordination, and cooperation between participating transplantation centres, tissue typing laboratories and the ANZKX Coordination Centre.
- 7 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 ANZKX Program Software 'MMEx' 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 (NRTLT, 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 (NRTLT, 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 and Program Coordinator in clerical and administrative tasks and communication;
- assist with the preparation and distribution of reports such as:
 - ANZKX matched pairs database
 - ANZKX Newsletters
 - ANZKX Annual Reports





- OTA Progress Reports
- RACOS minutes
- Reports to units following match runs
- assist with the management of data held by ANZKX including entry into database and analysis of data held in the database;
- · assist with management of ordering and supply of equipment.

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 (NRTLT) - New Zealand

NRTLT 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. NRTLT provides two NZ representatives to RACOS for the purposes of clinical oversight of the ANZKX. NZKAS is available via the link below:

https://www.health.govt.nz/system/files/documents/pages/nrts-nz-kidney-allocation-scheme-feb2019-final.pdf

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 matching at meetings 3-4 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 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.

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

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*)

ANZKX Registry on Medical Message Exchange (MMEx)

Medical Message Exchange (MMEx) is an eHealth platform designed as a simple and secure application that allows users to enter patient information, view relevant data and documents, and correspond with other MMEx users.

The role of the ANZKX Registry on MMEx is to provide an electronic platform for clinicians to register donor/recipient pairs, access ANZKX forms and documents, and enable communication between transplant centres and the ANZKX Coordination Centre.

The ANZKX Coordination Centre is the administrator of the ANZKX Registry, and user access is limited to designated nephrologists and renal transplant coordinators at participating transplant centres. Transplant centres will only be able to enter and view patient details from their own centre. The local Tissue Typing Laboratories have "read-only" access to view registrants for their State for the purpose of facilitating tissue typing requirements.

The ANZKX Coordination Centre as administrator is able to view all donor/recipient pairs on the registry, match potential pairs, and generate de-identified data from these matches that is forwarded to the relevant transplant centre clinicians.

For further information on the functionality of MMEx, please refer to the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program Registry User Manual on the MMEx portal.

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 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' (see section 5) 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 NRTLT 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 MMEx live donor report will be made available to the recipient's team.
- 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, NRTLT 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)
- 4 Donor/Recipient Registration Forms (if printed from MMEx)
- 5 ANZKX Tissue Typing Registration Form

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 View Report from MMEx

ANZDATA and post-transplant reporting

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

1 Living Kidney Donor Registry – Pre-Transplant Data form

Complete all data as required on form, leaving recipient details #9 and #10 blank.

9 ANZDATA RECIPIENT REGISTRY NUMBER	10 RECIPIENT SURNAME	RECIPIENT GIVEN NAMES	11 DONOR RELATIONSHIP TO RECIPIENT
			(Record from list on back of page)
Enter If known			OTHER

Enter # 15 (Paired Kidney Exchange) in **Donor Relationship to Recipient** box, and specify as **PKE**.

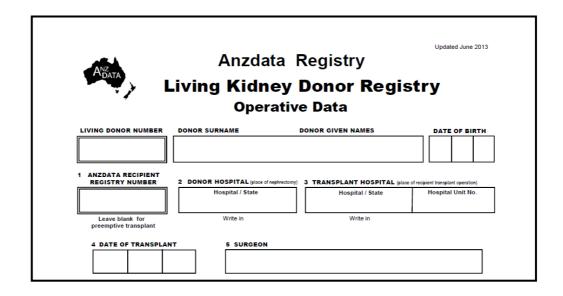
The ANZKX Coordination Centre will provide recipient details to ANZDATA, upon advisement of receipt of ANZDATA form.

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 ANZDATA Recipient Registry Number (Box 1) will not be available hence leave blank.

- Box 2 denotes the Donor Hospital the place of nephrectomy.
- Box 3 denotes the Transplant Hospital the place of recipient transplant surgery. This is in the majority of cases at a centre other than the Donor Hospital and can also potentially be in another State.





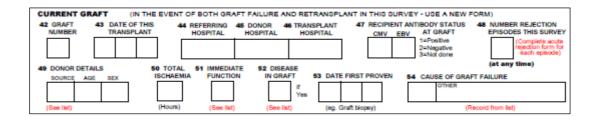


3 Real Time Web Data Entry

Notifying a change in treatment course i.e. transplantation, requires the same donor data as specified above. Please enter **Donor Source** as #15, **PKE**.

4 ANZ Dialysis & Transplant Survey sheet (for recipients)

Current Graft section: Question 49, **Source of Donor Kidney** enter as #15 from list (PKE). Other operative data required may be obtained as previously detailed in Point 2.



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

Who	Local Renal Specialist
Where	Local Renal Unit
What	Provide the recipient and their donor information on ANZKX including the Frequently Asked Questions form and Information for donors and recipients form. • If donor/recipient wish to consider ANZKX go to 2.

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

Who	Local Transplant Team Nephrologist
Where	Local Transplant Centre
What	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.
	If donor/recipient agree to ANZKX go to 3.

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 a Donor Declaration form in the presence of the interviewer (physician or nurse). The Donor Declaration is not submitted with Ministerial Approval 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

Who	Local Transplant Team Nephrologist	
Where	Local Transplant Centre	
What	Obtain signed copies of the Recipient Agreement to Participate and Donor Declaration form for the donor and recipient pair to participate in the ANZKX Program.	
	Submit the signed Recipient Agreement to Participate form and Donor Declaration form to the ANZKX Coordination Centre via MMEx upload, fax, or email.	

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

Who	Local Transplant Team Nephrologist	
Where	Local Transplant Centre	
What	 Complete Section 1 of the Ministerial Approval Form. Submit the Ministerial Approval form to the ANZKX Program Coordinator via MMEX upload, fax, or email. 	
Timing	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.

Who	Local Transplant Team Nephrologist
Where	Local Transplant Centre
What	Determine donor (and the recipient) medical suitability for the transplantation procedure according to the <i>Guidelines for evaluation of living donors for Paired Kidney Donation</i> .

Recommended guidelines for donor CT Angiogram protocol have been developed by ANZKX transplant surgeons and are provided at Protocol document 9.





5. Enter donor / recipient details into MMEx

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 on MMEx. 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 onto MMEx).

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

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. The ANZKX Coordination Centre can review images and might request further imaging if appropriate.

Who	Local Transplant Team Nephrologist/Renal Transplant Coordinator
Where	Local Transplant Centre
What	Enter data on donors and recipients into the ANZKX Registry via the web-based MMEx portal
	Forward a CD-ROM, USB (or electronic image transfer) of the donor's CT angiogram, plus CT report, to the ANZKX Coordination Centre.
	Send ANZKX Tissue Typing Registration Form to the relevant Australian state or New Zealand tissue typing laboratory.

It is important to submit the tissue typing registration form as soon as the donor-recipient pair have been deemed suitable for the program.

6. Immunology data entered into OrganMatch

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

For entry onto the PKD register:

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 (Tepnel) 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).

Who	Local Tissue Typing Officer
Where	Australian State & New Zealand Tissue Typing Laboratories





What	Enter donor/recipient immunology data (containing donor HLA type and recipient
	HLA type, sensitisation history and acceptable mismatches) into OrganMatch.

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 MMEx. Blood Group A donors are also required to be subtyped as this is important information for any potential Blood Group incompatible transplant.

Who	ANZKX Program Coordinator	
Where	ANZKX Coordination Centre	
	The ANZKX Coordination Centre will confirm that the referring transplant centre has fully evaluated the submitted donor/recipient pairs:	
	Donor medical work-up is complete;	
	The donor/recipient information is complete, including:	
	CD-ROM, USB (or electronic image transfer) and report of the donor CT angiogram have been received; and	
What	Donor/recipient pair immunology information has been completed.	
	If medical and immunology evaluation are complete, go to 8.	





Matching of pairs

8. Verification of active pairs

Who	ANZKX Program Coordinator	
Where	ANZKX Coordination Centre	
What	 ANZKX Program Coordinator to verify with Local Transplant Centres approximately monthly that: All active registered donor-recipient pairs are suitable for matching. Recipients have up-to-date HLA antibody testing and are suitable for transplantation. Acceptance of ABOi and Hepatitis B core positive donors as registered in MMEx is confirmed in accordance with recipient informed consent. Blood group A donors have been subtyped and subtype has been entered into MMEx. 	
	Donor blood group result (identified formal NATA accredited laboratory report) has been uploaded onto MMEx.	

9. Provide list of active pairs to ANZKX Tissue Typing Coordinator (ATTC)

Who	ANZKX Program Coordinator/ANZKX Tissue Typing Coordinator	
Where	ANZKX Coordination Centre	
	ANZKX Program Coordinator to:	
What	Send ANZKX Tissue Typing Coordinator a list of current active pairs weekly to ensure all immunological data is available, including sera for final cross match. The ATTC ensures OrganMatch data entry at local tissue typing laboratories has been completed.	

10. Matching

Who	ANZKX Tissue Typing Coordinator (ATTC)	
Where	ANZKX Coordination Centre	
	The ATTC will perform matching continuously throughout the year.	
	A report of matched donor/recipient pairs is sent to the ANZKX Coordination Centre.	
What	Recipients who have not been matched remain active on the transplant waiting list.	
	Recipients who have been matched to a suitable donor will be suspended from transplant waiting list.	
	They will be reactivated on the transplant waiting list if the chain breaks down.	





11. Review of matched pairs by ANZKX

Who	ANZKX Clinical Director/ Program Coordinator/ANZKX Tissue Typing Coordinator/HLA Laboratory Director/local TT officers	
Where	ANZKX Coordination Centre	
	Review matched donor-recipient pairs.	
What	Transplant centres may be contacted with potential match information as a preliminary enquiry towards acceptance/rejection of proposed match.	

12. Transplant teams notified of matched pairs

Who	ANZKX Program Director/Coordinator	ANZKX Tissue Typing Coordinator
Where	ANZKX Coordination Centre/Local Transplant Centre	All participating Australian state tissue typing laboratories and NZ tissue typing laboratories
What	 ANZKX Program Director/Coordinator: Notify transplant teams and Australian State/NZ TTL's of identified matched pairs. Centres are sent: Match pair review with details of immunological matching and donor specific antibodies. Match pair report with other donor information. Facilitates donor specific ABOi titre if required. Local Transplant Centre: Book XM within 5 days of notification. Recall matched donors to present to Transplant Centre for cross-matching. Repeat serology for HIV/HBV/HCV and CMV/EBV. 	 ANZKX Tissue Typing Coordinator: Coordinates cross matching with Australian state and NZ tissue typing laboratories to identify potential compatible pairs. Australian and New Zealand tissue typing laboratories: Prioritise ANZKX cross-matching. Cross matches are performed within 2 weeks.

13. Review of cross matches

Who	ANZKX Clinical Director/ANZKX Program Coordinator/ANZKX Tissue Typing Coordinator/Local Australian State and New Zealand TTL's
Where	ANZKX Coordination Centre





	Review crossmatch and flow cytometric crossmatch results.
	Approve acceptable exchanges following review of crossmatch results.
What	Appropriately de-identified cross match reports will be made available via OrganMatch.
	Notify state laboratories to re-activate recipients with positive cross-match on the transplant waiting list.

14. Surgical cross matching

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 and review 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 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 form is signed 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 checklists to all involved centres as confirmation of the exchange, two weeks prior to the agreed surgical date.

<u>Please note:</u> 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 viable 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.

Who	ANZKX Program Director/ Coordinator	Recipient and Donor Liaison Surgeons
Where	ANZKX Coordination Centre / Local Transplant Centre	Local Transplant Centres
What	ANZKX Program Coordinator: Sends CD-ROM/report of donor imaging to recipient liaison surgeon. Sends Surgical checklists to donor and recipient liaison surgeons.	Recipient & Donor Liaison Surgeons Complete and send Surgical Checklist to the ANZKX Coordination Centre.





Action Surgical Cross-Match result as required.	Advise the ANZKX Coordination Centre immediately if exchange not viable.
If proposed matches are acceptable, go to 15.	

15. Negotiation of transplant dates.

Concurrent with surgical 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.

<u>Please note:</u> 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.

16. Logistics for Exchange

Who	ANZKX Program Coordinator	
Where	ANZKX Coordination Centre	
What	Confirm date of surgery acceptable to Local Transplant Centres and donor/recipient pairs.	
	Inform the relevant Australian and New Zealand Tissue Typing Officers regarding the date of transplants.	
	Identify responsible person at each site that will oversee coordination of surgical timelines; and	
	Send a preliminary transport itinerary to transplant teams to assist with operative scheduling.	





Before Surgery

17. 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.

Who	ANZKX Program Coordinator and Local Transplant Team
Where	ANZKX Coordination Centre and Local Transplant Centre
What	ANZKX Program Coordinator to send ANZKX Transport Pack.
	The Local Transplant Centre to ensure ANZKX transport pack is available prior to a potential exchange and check that surgical schedules are in place.

18. 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.

Who	ANZKX Program Coordinator/Local Transplant Centre/ATTC/Local TT lab	
Where	ANZKX Coordination Centre	
	At least 4 weeks prior to surgery, ANZKX Program Coordinator will:	
	Remind transplant centres of necessity for collection of HLA serum.	
What	The ANZKX Tissue Typing Coordinator/Local TT lab will:	
	Review current SAB analysis.	
	Ascertain whether a further crossmatch is required.	

19. Consent for surgery and Donor Nucleic Acid Testing

Who	Local Transplant Centre/ANZKX Coordination Centre
Where	Local Transplant Centre
	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 ANZKX Surgical Checklist form.
What	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.
	Send result to ANZKX Coordination Centre as soon as available.
	The ANZKX Coordination Centre will forward de-identified NAT result to recipient centre.





If NAT results are negative, go to 20
If NAT results are positive, surgeries will be deferred

20. 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.

Who	ANZKX Program Coordinator
Where	ANZKX Coordination Centre
	Approximately one week prior to surgery ANZKX Program Coordinator confirms:
	ANZKX Transport Packs have been received by each centre.
	Anaesthetic start times and anticipated pick-up times for organs.
	Donor Blood request forms for "PKE store cells" and Living Kidney Donation reports have been sent to centres.
What	Name of recipient transplant surgeon who will be present in theatre to assist with packaging (as applicable).
	Flight itineraries for organs (as applicable).
	Transport Plan, NXF numbers & Consignment Notes for Organ Transport have been received by centres.
	Hospital pickup and delivery points and designated contacts at each hospital; and
	Back-up itinerary and emergency contact details.

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:

- OrganMatch Identification Numbers
- Date of Birth
- Blood Group

Who	ANZKX Program Coordinator
Where	ANZKX Coordination Centre
What	Verify that all items in step 20 are confirmed; and 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.	
Ensure de-identified copies of donor NAT, ABO & CMV/EBV documents are available at the donor centre.	

Surgery and post-surgery

22. Day of surgery

Who	Local Transplant Team
Where	Local Transplant Centre
	Confirm, in separate consultations, donor and recipients medical and emotional suitability to participate.
	Immediately notify the ANZKX Program Coordinator and other Local Transplant Centre if donor and/or recipient withdraw.
What	Notify the ANZKX Program Coordinator immediately of any last minute issue regarding consent, packaging, transport and surgery.
	For Donor Surgery, ensure that section 1 and 2 of the Living Kidney Donation Report is completed appropriately and accompanies the kidney, along with the donor blood samples and de-identified NAT, ABO and CMV/EBV results.
	For Recipient Surgery, ensure the kidney received is cross-checked and correct for the recipient prior to implantation.

23. After transplantation

Who	Recipient Surgical Team/ANZKX Program Coordinator
Where	Recipient Hospital/ANZKX Coordination Centre
	Recipient Surgical Team:
What	Complete section 3 of the Living Kidney Donation Report and forward to ANZKX Program Coordinator within two working days of procedure.
	ANZKX Program Coordinator:
	Feedback any issues to transplant centres and Organ and Tissue Authority.





24. Post-Transplant Notifications

Who	ANZKX Program Coordinator/Local Transplant Team
Where	ANZKX Coordination Centre/Local Transplant Centre
	ANZKX Program Coordinator:
	 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.
	Requests feedback of any issues.
What	Completes and forwards ANZDATA forms received to ANZDATA.
	Local Transplant Centre:
	Completes ANZDATA Living Donor Forms.
	 Provides post-transplant information as requested by ANZKX Coordination Centre.



