

Australian and New Zealand Paired Kidney Exchange Program

Protocol 5: Agreement to Participate & Ministerial Approval Process



Agreement to Participate & Ministerial Approval Process

The process for seeking donor and recipient agreement to participate differs in each jurisdiction based on legal requirements. The Agreement to participate and Ministerial Approval is outlined below by jurisdiction.

Queensland (QLD) and Victoria (VIC)

Agreement to participate

QLD and VIC Local Transplant Centres to:

- Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the ANZKX Program.
- Upload the signed Agreement to Participate Form to the KPD section of the OrganMatch Transplantation Portal.

Ministerial Approval

Ministerial Approval is not required for donors and recipients in Queensland and Victoria as ANZKX does not contravene Human Tissue Acts in these jurisdictions.

New South Wales (NSW) /Australian Capital Territory (ACT) / Tasmania (TAS) /Western Australia (WA)

Agreement to participate

NSW/ACT/TAS and WA Transplant Centres to:

- Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the ANZKX Program.
- Upload the signed Agreement to Participate Form to the KPD section of the OrganMatch Transplantation Portal.
- Once the Agreement to Participate is obtained, Ministerial Approval is required before the donor and recipient pair can be activated.

Ministerial Approval

Steps for obtaining Ministerial Approval in NSW:

- 1 Local Transplant Centre to complete Section 1 of the Ministerial Approval Form and email the completed approval form to the ANZKX Program Coordinator.
- 2 ANZKX Program Coordinator to complete Section 2 of the Ministerial Approval form.
- 3 ANZKX Coordination Centre to scan and upload a copy of the approval form including the class approval provided by the NSW delegate of the Minister of Health to OrganMatch.
- 4 ANZKX Coordination Centre to submit all approvals with a briefing note to the Office of the NSW Chief Health Officer on a quarterly basis.
- 5 Of note, individual review and approval is required for any non-standard applications relating to:
 - Minors
 - Donor/recipients who do not have capacity to consent to participate



- Participants seeking to enter the Program who are not NSW residents

Steps for obtaining Ministerial approval ACT/TAS/WA:

- 1 Local Transplant Centre to complete Section 1 of the Ministerial Approval Form and email the completed approval form to the ANZKX Program Coordinator.
- 2 ANZKX Program Coordinator to complete Section 2 of the Ministerial Approval form.
- 3 ANZKX Program Coordinator to send Approval Forms/Briefing Note to the relevant State Health Department.
- 4 Health Department Representative to forward Approval Form to the Minister for Health/Chief Health Officer or Delegate.
- 5 Minister for Health/Delegate to complete Section 3 of the Ministerial Approval Form and return the signed form (scanned and emailed) to the ANZKX Coordination Centre within 10 working days of receiving the form.
- 6 ANZKX Coordination Centre to scan and upload a signed copy of the approval form onto the KPD section of the OrganMatch Transplantation Portal and also forward a copy to the Local Transplant Centre via email.

Note that ACT participants also require approval from NSW Chief Health Officer as surgery will be performed in NSW.

South Australia (SA) / Northern Territory (NT)

Agreement to Participate

SA and NT Local Transplant Centres to:

- Once Ministerial Approval has been gained, the Local Transplant Centre can complete the Agreement to Participate Forms.
- Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the ANZKX Program.
- Upload the Signed Agreement to Participate Form to the KPD section of the OrganMatch Transplantation Portal.

Ministerial Approval

In SA and NT, Ministerial Approval must be gained before the Agreement to Participate Form is signed.

Steps for obtaining Ministerial Approval:

- 1 Local Transplant Centre to complete Section 1 of the Ministerial Approval Form and email the completed approval form to the ANZKX Program.
- 2 ANZKX Program Coordinator to complete Section 2 of the Ministerial Approval form.
- 3 ANZKX Program Coordinator to send Approval Forms and Briefing Note to the State Health Department.
- 4 SA Health Department Representative to confirm that the Ministerial Instrument of Approval provided under section 35(6) of the *Transplantation and Anatomy Act 1983* applies for the donor-recipient pair.
- 5 SA Health Department Representative to complete Section 3 of the Ministerial Approval Form and return the signed form (scanned and emailed) to the ANZKX Coordination Centre within 10 working days of receiving the form.
- 6 ANZKX Coordination Centre to email a signed copy of the approval form to the Local Transplant Centre.



7 Once the Local Transplant Centre receives the signed copy of the approval form, Donor and Recipient Agreement to Participate can be obtained.

Note: If the Agreement to Participate is signed in the NT approval must be sought from both the NT Minister for Health and SA Health Department Representative, and both representatives are required to sign Section 3 of the Ministerial Approval Form.

Final note for all jurisdictions

If participants withdraw their approval and subsequently re-enter the ANZKX Program there will need to be a new approval given.



Australian and New Zealand Paired Kidney Exchange Program – Sample draft briefing note for ACT, TAS, NSW, WA, SA and NT

Date: _____

1 ISSUE

Participation in the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program.

Type of briefing

For information and ministerial approval of a donor-recipient pair or non-directed altruistic donor to participate in the ANZKX Program in accordance with the relevant State Human & Tissue Transplant Act.

Reason for briefing

Approval of the entering into of a contract or arrangement that may result in a paired kidney donation between incompatible donor-recipient pairs, that would, but for the approval, be void under the State Human & Tissue Transplant Act.

2 BACKGROUND

- The increasing demand for donated kidney organs for transplantation and the deceased organ donor numbers necessitate the alternative of living kidney donation to meet demand.
- Successful kidney transplantation is the best treatment clinically for suitable candidates and it is highly cost effective for end stage kidney failure, with long term results from living donor transplants being far superior to those from deceased donors.
- However, 30% of potential donors fail to fulfil their wish to donate to a family member or friend due to a blood group or immunological incompatibility. The ANZKX Program is one option for utilising available organs from live donation, in an environment of critical shortage of donated cadaveric organs and ever-increasing demand for transplantation.
- Formal Paired Kidney Donation programs operate in the Netherlands, Korea, United States, and in the United Kingdom.
- The Australian Paired Kidney Exchange (AKX) began in 2010 and has been very successful at facilitating transplantation between pairs within Australia. A similar national program was established in New Zealand, the New Zealand Kidney Exchange Program (NZKE), in 2009. In 2019 the 2 national programs joined to create the Australian and New Zealand Paired Exchange Program (ANZKX) with the goal to facilitate living donor kidney transplantation within and between both countries. The goal of joining the two programs was to increase the ability to match and transplant patients in both countries.

3 CURRENT STATUS

- The ANZKX Program is an extension of existing and established technology for live donor kidney transplantation. Kidney transplantation from a live donor accounts for 24% of kidney transplantation in Australia and approximately 40% in New Zealand.
- Any patient with end stage kidney disease who is eligible for a kidney transplant is able to participate in the ANZKX Program. Potential recipients must have a living donor who is willing but unable to donate because of an incompatible blood group or tissue type. The donor must also be willing to take part and to donate his or her kidney to someone else.
- Pairs without blood group or tissue type incompatibility are also able to enter the program to try to obtain better tissue matching to improve the long term outcome of the transplant.



- Non-directed altruistic donors are people who have expressed a wish to donate a kidney but do not have a specified recipient. These donors can be entered into the ANZKX program and are able to start a chain of transplants that ends with the final donor donating their kidney to a recipient on the transplant waiting list.
- Transplantation of incompatible donor-recipient pairs by ANZKX is dependent on accurate and reproducible tissue typing results and data entry. It is based on recognising acceptable HLA antigen mismatches and dedicated Tissue Typing laboratories in each State provide this information, with the assistance of the ANZKX Tissue Typing Coordinator.

4 BENEFITS OF THE PROGRAM

- 1 Saving more lives of Australians and New Zealanders on dialysis waiting for a kidney.
- 2 Giving a larger number of renal patients the opportunity for a better quality of life and the ability to earn an income.
- 3 Reducing the demand on hospital resources usually required for patients on dialysis.
- 4 Avoiding costs that would be necessary to support patients who would remain on dialysis (average annual costs per patient are approximately \$65,000 for dialysis at a dialysis centre or \$49,000-\$53,000 for home dialysis, depending on the type) instead of the cheaper option of kidney transplantation (average annual costs ~\$12,000 per patient per year, after the first year).

Recommendation(s)

The Minister for Health or their delegate:

- 1 Notes the above information; and
- 2 Approves the participation of the donor-recipient pair in the Australian and New Zealand Paired Kidney Exchange Program.

Contact for further information:

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 Email: ANZKX@mh.org.au

Or your State Jurisdictional Representative



VERSION CONTROL			
Version	Date	Author	Comments
V 1.0	Jul 2019	ANZKX Team	AKX 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
V 4.0	Apr 2023	ANZKX Team, SA Health & Office of NSW Chief Health Officer	Updates made to the New South Wales (NSW) and South Australian (SA) Ministerial Approval process

