

13 KIDNEY PAIRED DONATION

13.1 Scope of Policy

Unless otherwise stated, references to potential donors and donors within this policy are specific to KPD potential donors and donors and references to candidates and recipients are specific to KPD candidates and recipients.

13.2 Requirements for Participation in the OPTN KPD Program

13.2.1 Candidates

In order to participate in the OPTN KPD program, candidates must be registered on the deceased donor kidney waiting list at the Transplant Hospital that wishes to enroll the candidate in the OPTN KPD Program.

13.2.2 Potential Donors

In order to participate in OPTN KPD Program, potential donors must comply with *all* of the following requirements:

1. Be aged at least 18 years old
2. Not be currently listed as a potential donor for any other candidate registered in the OPTN KPD Program

13.3 Informed Consent for Candidates

Reserved

13.4 Informed Consent for Potential Donors

Reserved

13.5 Histocompatibility Testing

Reserved

13.6 Matching Within the OPTN KPD Program

13.6.1 Requirements for Match Run Eligibility for Candidates

The OPTN KPD Program will only match candidates that comply with *all* of the following requirements:

1. The candidate's Transplant Hospital must comply with Policy 3.1.2
2. The candidate's Transplant Hospital must complete the informed consent process per KPD Operational Guidelines
3. The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor
 - a. Candidate Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender

- Ethnicity/Race
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD Program
 - Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor
 - KPD status
- b. Candidate Choices
- Whether the candidate would be willing to travel, and, if so, the Transplant Hospitals to which a candidate would be willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which Transplant Hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
4. The candidate must be in an active status in the OPTN KPD Program
 5. The candidate must have at least one ~~and no more than two~~ active and eligible potential donor registered in the OPTN KPD Program
 6. The candidate's Transplant Hospital must submit a response for all previous match offers for the candidate in the OPTN KPD Program
 7. The candidate must not be in a pending exchange in the OPTN KPD Program

13.6.2 Requirements for Match Run Eligibility for Potential Donors

The OPTN KPD Program will only match potential donors that comply with *all* of the following requirements:

1. The Transplant Hospital registering the potential donor in KPD must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications
 - a. The Transplant Hospital registering the potential donor in KPD must report the potential donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential donor's actual blood type to the OPTN Contractor
 - c. The potential donor is not eligible for a KPD match run until the Transplant Hospital reports two identical blood types
2. The Transplant Hospital registering the potential donor in KPD must complete the informed consent process per KPD Operational Guidelines

3. The Transplant Hospital registering the potential donor in KPD must complete the medical evaluation process per KPD Operational Guidelines
4. The Transplant Hospital registering the potential donor in KPD must submit the required fields below to the OPTN Contractor
 - a. Donor Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Height and weight
 - Whether the potential donor is a non-directed donor;
 - If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate
 - Whether the potential donor has signed an agreement to participate in the OPTN KPD Program
 - Whether the potential donor has signed a release of protected health information
 - Whether the potential donor has signed an informed consent as required in policy
 - Whether the potential donor has undergone a medical evaluation as required in policy
 - Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status
 - b. Clinical Information
 - The number of anti-hypertensive medications the donor is on
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance, date, and method
 - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
 - c. Donor Choices
 - Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel
 - Whether the potential donor is willing to ship a kidney
 - Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain
 - Whether the potential donor and the Transplant Hospital are willing for the potential donor to be a bridge donor
5. The potential donor must be in an active status in the OPTN KPD Program
6. The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program

7. The Transplant Hospital registering the potential donor in KPD must submit a response for all previous match offers for the potential donor in the OPTN KPD Program
8. The potential donor must not be in a pending exchange in the OPTN KPD Program.

13.6.3 Screening Criteria

13.6.3.1 Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in Table 13-1. Fields with a “●” indicate identical blood type matches. Fields with a “◐” indicate permissible blood type matches. Fields with a “◑” indicate permissible blood type matches providing the candidates meets the requirements in Policy 13.6.3.2. Fields with a “○” indicate impermissible blood type matches.

		Candidate's Blood Type			
		O	A or A ₁ or A ₂	B	AB or A ₁ B or A ₂ B
Donor's Blood Type	O	●	◐	◐	◐
	A	○	●	○	◐
	A ₁	○	●	○	◐
	A ₂	◐*	●	◐*	◐
	B	○	○	●	◐
	AB	○	○	○	●
	A ₁ B	○	○	○	●
	A ₂ B	○	○	◐*	●

Table 13-1: Blood Typing for KPD

13.6.3.2 A₂ and A₂B Matching

In order for a blood type B candidate to be eligible to be matched to a blood type A₂ or A₂B potential donor, or for a blood type O candidate to be eligible to match to a blood type A₂ potential donor in the OPTN KPD Program, *all* of the following conditions must be met:

1. The candidate must have an IgG antibody titer value less than 1:8
2. The candidate's Transplant Hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

13.6.3.3 Unacceptable Antigens

A Transplant Hospital may specify any unacceptable antigens it will not accept for its candidates. The OPTN Contractor will not match the candidate

with any potential donor who has one of the candidate's unacceptable antigens entered as an HLA value.

13.6.3.4 Candidate and Potential Donor Choices

A Transplant Hospital may specify criteria it will not accept for any of its candidates as outlined in Policy 13.6.1-3(b) or potential donors as outlined in Policy 13.6.2-6(c). The OPTN Contractor will not match the candidates with potential donors who fall outside the specified criteria or potential donors with candidates who fall outside the specified criteria.

13.6.4 Prioritization Points

Reserved

13.6.5 Two- and Three-Way Matches

13.6.5.1 Match Size

The OPTN Contractor will match donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor as outlined in Policy 13.6.6.

13.6.5.2 Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD Program, all donor surgeries involved in the exchange must begin on the same day and only after all donor surgeons involved in the exchange agree to proceed.

13.6.6 Donor Chains

13.6.6.1 Chain Size

In the OPTN KPD Program, ~~donor chains will be limited to 20 donor-candidate pairs~~ there is no limit on the length of the donor chains.

13.6.6.2 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain or with a bridge donor who will be included in a later match run. The Transplant Hospital that enters the NDD can choose whether the chain can end with a bridge donor or whether the chain must end with a donation to a candidate on the waiting list at that Transplant Hospital. The Transplant Hospital registering the potential donor in KPD may refuse to allow the potential donor to serve as a bridge donor at any point in the process.

13.6.6.3 What to Do When a Chain Breaks

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in Policy 13.6.6.2. ~~be entered in the next match run to repair the donor chain if all of the following conditions are met:~~

- ~~1. The operating room dates are not set for a chain at the time of the next match run~~
- ~~2. The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match~~
- ~~3. The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.~~

13.7 Crossmatching Protocol

The candidate's Transplant Hospital must perform a preliminary crossmatch for candidates in the OPTN KPD Program before the matched donor's recovery procedure.

The Transplant Hospital registering the potential donor in KPD is responsible for shipping the potential donor's blood sample to the matched candidate's Transplant Hospital or the laboratory specified by the matched candidate's Transplant Hospital.

The candidate's Transplant Hospital is responsible for running the crossmatch and reporting the results to the OPTN Contractor and the matched donor's Transplant Hospital.

13.8 Transportation of Kidneys

For any KPD exchange, the recovery Transplant Hospital is responsible for packaging, labeling, and transporting kidneys from donors as provided in Policy 12.7.

In the OPTN KPD Program, the recipient's Transplant Hospital must specify the location where the recovery Transplant Hospital must deliver the kidney. The recovery Transplant Hospital must then document the name and telephone number of every person or company who will package, label, or transport the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the recipient's Transplant Hospital along with the date and time that the name is documented. The recovery Transplant Hospital must complete this documentation before the potential donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.9 Rules for When Donors and Recipients Can Meet

The following rules apply to meetings facilitated by an OPTN Member between donors and matched recipients that participated in an OPTN KPD Program exchange. These rules do not apply to meetings between potential donors and paired candidates.

Members can facilitate a meeting between donors and recipients that participated in an OPTN KPD Program exchange only if *all* of the follow conditions are met:

1. All the donors and recipients participating in the meeting agree to meet
2. The meeting occurs after the transplant concludes
3. The Transplant Hospital establishes a written protocol for when donors and recipients can meet. This protocol must include, at a minimum, the timing of the meeting and what staff must attend the meeting.
4. Transplant Hospital complies with their written protocol for when donors and recipients can meet. The Transplant Hospital must maintain documentation of compliance in the donor's or recipient's medical record.

13.10 Definitions

- *Bridge donor* – a donor who does not have a match identified during the same match run as his paired candidate.
- *Chain* – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.
- *Exchange* – a set of matches that form a chain, a two-way exchange, or a three-way exchange.
- *Match* – a donor and his matched candidate
- *Match Run* – procedure used to generate a set of exchanges
- *Matched candidate* – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney
- *Matched donor* – a donor identified by a KPD match run as a potential donor for a candidate
- *Matched recipient* – a matched candidate that has received a transplant
- *Non-Directed Donor (NDD)* – a donor that enters KPD without a paired candidate
- *Other antibody specificities* – antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.
- *Pair* – a donor and his paired candidate
- *Paired candidate* – the candidate to whom a donor intended to donate his organ before entering into KPD
- *Paired Donation of Human Kidneys (KPD)* – the donation and receipt of human kidneys under the following circumstances:
 - An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.
 - A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
 - The first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.
 - If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
 - All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
 - Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.

- *Paired donor* – a donor who intended to donate his organ, before entering into KPD, to his paired candidate
- *Paired Recipient* – a paired candidate that has received a transplant
- Transplant Hospital registering the potential donor in KPD – the Transplant Hospital that enters the potential donor in a KPD program
- *Three-way exchange* – a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.
- *Two-way exchange* – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.
- *Unacceptable antigens* – antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens.