

# ***Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy***

<b>Sponsoring Committee:</b>	<b>Kidney Transplantation Committee</b>
<b>Policy/Bylaws Affected:</b>	<b>Bylaws Appendix E.5 Kidney Transplant Programs that Perform Living Donor Recovery; and Policies 13.5.C (HLA Typing Requirements for OPTN KPD Donors), 13.7.E (Prioritization Points), 13.7.F (OPTN KPD Waiting Time Reinstatement), 13.9.B (Logistical Requirements), 13.10 (Crossmatching Protocol), 13.11 (Transportation of Kidneys), and 13.12 (Communication between KPD Donors and Recipients)</b>
<b>Distributed for Public Comment:</b>	<b>September 2015</b>
<b>Amended After Public Comment:</b>	<b>Yes</b>
<b>Effective Date:</b>	<b>September 1, 2015, except for Policy 13.11 (Receiving and Accepting Match Offers) which is effective pending programming</b>

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## **Problem Statement**

The OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) is transitioning from a pilot program to a permanent program. As such, the Kidney Committee and Board of Directors believe it is appropriate to continue transitioning sections of the operational guidelines into OPTN Policy. Including these sections in OPTN Policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN/UNOS. We previously transitioned other sections of the operational guidelines to OPTN Policy in November 2012 and June 2014.

## **Summary of Changes**

These policy changes aim to make the KPDPP's matching process more efficient, by ensuring that transplant hospitals respond to offers and perform exchange responsibilities in a timely fashion, and by requiring the pre-selection of donors for sensitized candidates in order to avoid futile match offers.

## **What Members Need to Do**

Once the transition is implemented on September 1, 2015, any transplant programs participating in the KPDPP must pre-accept any potential donors shown for candidates with a CPRA greater than or equal to 90 percent to potentially receive an offer from that donor. Any donors that are not pre-accepted will be

treated as pre-refused. Candidates do not receive offers from pre-refused donors. Pre-refusals and pre-acceptances may be entered for candidates with a lower CPRA; while doing so is not mandatory, it will make the match process more efficient.

Every transplant program participating in the KPDPP must appoint a KPD contact and alternate, and report their contact information to UNOS. The deadlines established in *Policy 13.11: Receiving and Accepting KPD Match Offers* will be effective pending programming. The KPD contact must become familiar with all of the deadlines triggered by the receipt of a match offer. This ensures that exchanges in which their candidates or donors are participating do not terminate because of missed deadlines.

You will be expected to accurately report data based upon the proposed language. However, the proposed language will not change the way UNOS currently monitors members. Any data entered in UNet<sup>SM</sup> may be subject to OPTN review, and you must provide documentation, if we request it.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## **OPTN Bylaws**

### **F. Kidney Paired Donation (KPD)**

~~Members~~ Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate kidney paired donation ~~KPD~~ contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.
4. ~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules (Operational Guidelines). Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

## **OPTN Policies**

### **13.5.C HLA Typing Requirements for OPTN KPD Donors**

Before a ~~paired~~ donor can appear on an OPTN KPD match run, the ~~paired~~ donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6

- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DQA
- HLA-DQB
- HLA-DPB

### **13.7.E Donor Pre-Acceptance and Pre-Refusal**

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must pre-accept or pre-refuse potential donors. The OPTN KPD candidate will only be matched with donors that are pre-accepted. If a donor is not pre-accepted, the donor will automatically be treated as pre-refused and will not be matched with the candidate.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital has the option to pre-accept or pre-refuse potential donors. These candidates will automatically be matched with all potential donors, unless the candidate's transplant hospital exercises the option to pre-refuse a potential donor.

### **13.7.EF Prioritization Points**

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

**Table 13-2: OPTN KPD Prioritization Points**

<b>If the:</b>	<b>Then the match will receive:</b>
Candidate is a 0-ABDR mismatch with the potential donor	200 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate is a prior living organ donor	150 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate and potential donor are registered for the OPTN KPD program in the same region	25 points
Candidate and potential donor are registered for the OPTN KPD program in the same DSA	25 points

If the:	Then the match will receive:
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	25 points
Potential donor has at least one of the other antibody specificities reported for the candidate	- 5 points

### 13.7.FG OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

1. Kidney graft removal within the first 90 days of transplant documented by a report of the removal of the transplanted kidney.
2. Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days of the kidney transplant.

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

### 13.9.B Logistical Requirements

In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate must receive a kidney within 24 hours of the same day his paired KPD donor donates. A KPD candidate-donor pair will always have the option to have surgery on the same day. KPD 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 KPD candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor that started that chain or with a KPD 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 a donation to the deceased donor waitlist. The transplant hospital registering the potential KPD donor may refuse to allow the potential KPD donor to serve as a bridge donor at any point in the process.

## 13.10 OPTN KPD Crossmatching Protocol Requirements

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has occurred.

~~The paired donor's transplant hospital is responsible for arranging shipment of the paired KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.~~

The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.

## **13.11 Receiving and Accepting KPD Match Offers**

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

**Table 13-3: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer**

<b><u>The following members:</u></b>	<b><u>Must:</u></b>	<b><u>Within:</u></b>
<u>Each transplant hospital receiving a match offer</u>	<u>Report to the OPTN Contractor a preliminary response</u>	<u>2 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital and the matched donor's transplant hospital</u>	<u>Agree in writing upon all of the following:</u> <ul style="list-style-type: none"> <li>• <u>contents required in the crossmatch kit</u></li> <li>• <u>instructions for the donor</u></li> <li>• <u>address at which to send the completed blood samples</u></li> </ul>	<u>4 business days of receiving the match offer.</u>
<u>The matched donor's transplant hospital</u>	<u>Report to the OPTN Contractor the agreed upon date of the crossmatch</u>	<u>4 business days of receiving the match offer.</u>

<u>The following members:</u>	<u>Must:</u>	<u>Within:</u>
<u>The matched donor's transplant hospital</u>	<p><u>Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:</u></p> <ul style="list-style-type: none"> <li>• <u>any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital</u></li> <li>• <u>whether the matched donor is increased risk according to the <i>U.S Public Health Services (PHS) Guideline</i></u></li> <li>• <u>additional records requested by the matched candidate's transplant hospital</u></li> </ul>	<u>4 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital</u>	<u>Report to the OPTN Contractor the results of the crossmatch</u>	<u>15 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital</u>	<u>Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor</u>	<u>15 business days of the match offer.</u>

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

### **13.11.A Requesting a Deadline Extension for a KPD Exchange**

The transplant hospital may request an extension for any of the deadlines in Table 13-3 by submitting a request in writing to the OPTN Contractor. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension within 2 business days. If all other transplant hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN Contractor will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will not be granted and the exchange will be terminated.

## **13.142 Transportation of Kidneys**

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.2: Organs Recovered by Living Donor Recovery Hospitals*.

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

### **13.123 Communication between KPD Donors and Recipients**

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

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the following conditions are met:

1. All the KPD donors and recipients participating in the communication agree on the conditions of the meeting or correspondence.
2. The meeting or correspondence occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. ~~The~~ The transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.