

Notice of OPTN Policy Change

Update Kidney Paired Donation Policy

Sponsoring Committee:	Kidney Transplantation
Policies Affected:	<i>1.2: Definitions</i> <i>13.3: Informed Consent for KPD Candidates</i> <i>13.4: Informed Consent for KPD Donors</i> <i>13.4.D: Additional Requirements for Non-Directed Donors</i> <i>13.4.E: Additional Requirements for Bridge Donors</i> <i>13.7.G: OPTN KPD Waiting Time Reinstatement</i> <i>13.11: Receiving and Accepting KPD Match Offers</i> <i>13.11.A: Requesting a Deadline Extension for a KPD Exchange</i>
Public Comment:	August 3, 2022 – September 28, 2022
Board Approved:	December 5, 2022
Effective Date:	February 1, 2023

Purpose of Policy Changes


OPTN KPD Policy was last updated in 2019. Since that time, KPD practice has evolved, and changes are warranted to clarify and bring OPTN KPD Policy up to date. The purpose of these changes is to align *OPTN Policy 13: Kidney Paired Donation* with other OPTN policies, clarify language and requirements, bring administrative OPTN KPD policies up to date with current practice, and to increase efficiency within the KPD match offer, exchange, and transplant processes. These policy changes also include updates to KPD informed consent requirements to improve clarity and emphasize donor autonomy. Finally, administrative requirements for the OPTN KPD Pilot Program (OPTN KPDPP) were updated to align with current practices and improve program efficiency.

Proposal History

The OPTN KPD Workgroup re-formed in 2021 with representation from the following OPTN Committees:

- Kidney Transplantation
- Living Donor
- Histocompatibility
- Minority Affairs
- Patient Affairs
- Transplant Coordinators
- Transplant Administrators

The Workgroup performed a holistic review of *OPTN Policy 13: Kidney Paired Donation*, identifying language in need of clarification and alignment with current practices and other relevant parts of OPTN policy. During this review, the Workgroup determined several small policy modifications were



appropriate to improve efficiency and clarity in KPD processes. Many of these modifications were submitted for public comment and board approval in the summer and fall of 2022.

Summary of Changes

This policy change will update informed consent policies and OPTN KPDPP administrative policies, and include several minor language clarification updates.

Changes to informed consent policies include all of the following:

- Clarification that *OPTN Policy 13.3: Informed Consent to KPD Candidates* and *OPTN Policy 13.4: Informed Consent for KPD Donors* apply to donors and candidates in any KPD exchange, unless otherwise specified
- Updates to informed consent requirements for KPD donors, to align with OPTN Living Donor informed consent policies and emphasize financial risk and potential resources available to defray costs associated with living donation
- Require transplant hospitals to obtain the living donor's signature confirming that the paired donor has been informed that they may withdraw from participation in the KPD program at any time, for any reason

This policy change will also include updates to language related to bridge donors:

- Updated definition of "Bridge Donor" for clarity and to emphasize donor autonomy
- Require programs to inform the bridge donor of all the options for donation available to them, as well as their right to decline to donate at any time, for any reason
- Require programs to inform bridge donors that they may determine how long they are willing to wait to be a bridge donor, and that they may revise this estimate at any time
- Removing the requirement for transplant programs to provide an estimate of how long the bridge donor is willing to wait

OPTN KPDPP match offer and exchange deadline modifications include:

- The hospitals involved in the exchange must agree in writing upon the contents required in the crossmatch kit, instructions for the donor, and the addresses at which to send completed blood samples **within three business days, shortened from the current deadline of four business days**
- The hospitals involved in the exchange must report the agreed upon date of the crossmatch and make the matched donor's records accessible to the matched candidate's transplant hospital **within three business days, shortened from four business days**
- The candidate's transplant hospital must report to the OPTN results of the crossmatch, review the matched donor's records, and confirm acceptance or report a refusal of the match offer to the OPTN **within 10 business days, shortened from 15 business days**

This policy change also introduces two new deadlines to the OPTN KPDPP:

- The matched candidate’s transplant hospital and the matched donor’s transplant hospital must agree upon a date and time for the recovery of the matched kidney **within 15 business days of receiving the match offer**
- The transplant hospitals participating in the exchange must schedule both the recovery of the kidney from one of the matched donors in the exchange and the subsequent transplant of their matched candidate to occur **within 60 calendar days of receiving the match offer**

The policy changes will include an update to the OPTN KPDPP extension request policy, such that the program’s requested extension is granted if any of the other transplant hospitals in the exchange fail to respond.

Finally, the policy changes include some minor clarifications and modifications. This update will clarify that requirements laid out in *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors* apply to non-directed donor participants in any KPD program and remove reference to the donor’s donation service area. These changes will align OPTN KPDPP Waiting Time Reinstatement policy with that for general kidney waiting time reinstatement.

Implementation

This policy change includes updates to informed consent requirements. Transplant programs participating in any KPD program will need to ensure their candidates and living donors are appropriately consented and appropriate documentation maintained.

This policy change will have specific impact on transplant program participants in the OPTN KPDPP. Participating transplant programs will need to coordinate with staff to ensure match offer review requirements are completed within the updated deadlines. Participating transplant programs will also need to coordinate and organize with each other to ensure the proposed recovery and transplantation deadlines are met.

This policy change shortens deadlines related to crossmatching and reporting crossmatching results. This is expected to have minimal impact on Histocompatibility Laboratories, who will need to ensure typing materials are processed and cross-matched in a timely manner.

This policy change will not require information technology implementation. OPTN Policy will be updated appropriately, as will current educational offerings for participating transplant programs.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

1.2 Definitions

Bridge donor

A Kidney Paired Donation (KPD) donor ~~who does not have a match identified during the same match run as the donor's paired candidate and continues a chain in a future match run~~ at the end of a KPD Chain who chooses to participate in future KPD match runs.

13.3 Informed Consent for KPD Candidates

The below requirements apply to candidates participating in any KPD program, unless otherwise specified. (Leads into subsections)

13.4 Informed Consent for KPD Donors

The below requirements apply to donors participating in any KPD program, unless otherwise specified. (Leads into subsections)

13.4.C *Additional Requirements for KPD Donors*

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
8. The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. ~~The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital~~
11. The possibility that personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation related costs.
12. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
13. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
14. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney

15. That the paired donor may require additional testing, including multiple blood draws for crossmatching
16. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

The paired donor's transplant hospital must obtain the paired donor's signature that confirms the donor has been informed that the paired donor may of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4.D *Additional Requirements for Non-Directed Donors (NDD) Participants in KPD Programs*

For any KPD exchange, before a NDD can participate in the KPD program, the NDD's transplant hospital must document in the NDD's medical record that it has informed the NDD of all their donation options including:

1. Participating in KPD
2. Donating to a candidate waiting for a deceased donor kidney according to *Policy 14.6.B: Placement of Non-directed Living Donor Organs*
3. Any other options available ~~in the NDD's donation service area~~ to the NDD

13.4.E *Additional Requirements for Bridge Donors*

For any KPD exchange, before a bridge donor is entered into a KPD match run, the bridge donor's transplant hospital is responsible for obtaining and maintaining documentation in the donor's medical record that it has informed the bridge donor of all the following:

1. The bridge donor may need to have another medical evaluation at a future time.
2. The bridge donor may need to be available to provide blood on multiple occasions for crossmatching.
3. How the KPD program determines whether a chain ends with a bridge donor
4. The bridge donor may decline to donate at any time, for any reason
5. All of the bridge donor's options for donation, including:
 - a. Continued participation as a bridge donor in the KPD program
 - b. Donation to a candidate waiting for a deceased donor kidney
 - c. Any other options available to the bridge donor
6. ~~Approximately how long the bridge donor can expect to wait before undergoing surgery to recover the bridge donor's kidney, based on the experience of the bridge donor's transplant hospital. The bridge donor will have the option to revise the estimated amount of time the donor is willing be a bridge donor based on this information. The bridge donor determines the amount of time the donor is willing to be a bridge donor.~~ The bridge donor determines the amount of time the donor is willing to be a bridge donor. The bridge donor's transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor. If the bridge donor revises the amount of time the donor is willing to be a

bridge donor, the bridge donor’s transplant hospital must document that revision in the donor’s medical record.

The bridge donor’s transplant hospital must maintain documentation in the donor’s medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted KPD exchange.

13.7.G 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 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 with another living donor. 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 after the candidate’s kidney transplant.

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

13.11 ~~Receiving and Accepting KPD Match Offers~~ KPD Match Offer and Transplant Timing Requirements

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

Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN a preliminary response	2 business days of receiving the match offer.
The matched candidate’s transplant hospital and the matched donor’s transplant hospital	Agree in writing upon all of the following: <ul style="list-style-type: none"> • Contents required in the crossmatch kit • Instructions for the donor • Address at which to send the 	4 <u>3</u> business days of receiving the match offer.

The following members:	Must:	Within:
	completed blood samples	
The matched donor's transplant hospital	Report to the OPTN the agreed upon date of the crossmatch	4 3 <u>10</u> business days of receiving the match offer.
The matched donor's transplant hospital	<p>Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:</p> <ul style="list-style-type: none"> • Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital • Whether the matched donor has any risk criteria for acute HIV, HBV, or HCV infection according to the <i>U.S. Public Health Service (PHS) Guideline</i> • Additional records requested by the matched candidate's transplant hospital 	4 3 <u>10</u> business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN the results of the crossmatch	15 <u>10</u> business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN	15 <u>10</u> business days of receiving the match offer.
<u>The matched candidate's transplant hospital and the matched donor's transplant hospital</u>	<u>Agree upon a date and time for the recovery of the matched kidney(s)</u>	<u>15 business days of receiving the match offer</u>
<u>The matched donor's transplant hospital and matched candidate's transplant hospital</u>	<u>Schedule both the recovery of the kidney from one of the matched donors in the exchange and the subsequent transplant of their matched candidate to occur</u>	<u>60 days of receiving 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 13-4* by submitting a request in writing to the OPTN. 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 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 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~~ will be granted.