

## *Public Comment Proposal*

# Update Kidney Paired Donation Policy

*OPTN Kidney Transplantation Committee*

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# Update Kidney Paired Donation Policy

<i>Affected Policies:</i>	<p>1.2: Definitions</p> <p>13.3: Informed Consent for KPD Candidates</p> <p>13.4: Informed Consent for KPD Donors</p> <p>13.4.D: Additional Requirements for Non-Directed Donors</p> <p>13.4.E: Additional Requirements for Bridge Donors</p> <p>13.7.G: OPTN KPD Waiting Time Reinstatement</p> <p>13.11: Receiving and Accepting KPD Match Offers</p> <p>13.11.A: Requesting a Deadline Extension for a KPD Exchange</p> <p>14.6.B: Placement of Non-Directed Living Donor Organs</p>
<i>Sponsoring Committee:</i>	Kidney Transplantation
<i>Public Comment Period:</i>	August 3, 2022 – September 28, 2022

## Executive Summary

The OPTN’s Kidney Paired Donation Pilot Program (KPDPP) has been operational since 2010 and is governed by *OPTN Policy 13: Kidney Paired Donation*. Kidney Paired Donation (KPD) is a process that matches one medically incompatible living donor-candidate pair with another, so the donor in each pair is medically compatible with the candidate in the other pair. By exchanging living donors, each candidate can receive a compatible transplant. These “exchanges” can consist of several candidate-donor pairs, creating KPD “chains.”<sup>1</sup>

The OPTN Kidney Transplantation Committee (the Committee) proposes a series of minor modifications to OPTN KPD policy to provide clarity, align policy language with other OPTN policies, and improve efficiency of the OPTN KPDPP program. The proposed modifications will:

- Shorten match offer and evaluation deadlines
- Establish recovery and transplant deadlines
- Adjust administrative policies to prevent termination of exchanges due to administrative lapses
- Update informed consent policies to provide clarity, emphasize donor autonomy, and align requirements with those in OPTN Living Donor policy

This proposal is an initial step towards bringing KPD policy up to date and improving the efficiency of the OPTN KPDPP.

<sup>1</sup> Kidney Paired Donation, United Network for Organ Sharing. <https://unos.org/transplant/kidney-paired-donation/>.

## Purpose

OPTN KPD Policy was last updated in 2015. Since that time, the practice of KPD has evolved, and changes are warranted to clarify and bring KPD Policy up to date. The purpose of this proposal 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 practices, and to increase efficiency within the KPD match offer, exchange, and transplant processes. This proposal includes updates to KPD informed consent requirements, to improve clarity and emphasize donor autonomy. This proposal will also update administrative requirements for the OPTN KPDPP, to align with current practices and improve program efficiency.

## Background

The original OPTN KPD Workgroup (the Workgroup) formed in 2004, and developed a pilot national KPD program. This program, the OPTN KPDPP, became operational in 2010.<sup>2,3</sup> Over the last decade, the Workgroup has monitored the progress of the OPTN KPDPP, developing proposals to update policy as necessary to improve the success of the program.

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 reviewed each section of *OPTN Policy 13: Kidney Paired Donation*, identifying areas 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, clarity, and fairness in KPD processes.

## Overview of Proposal

The Committee proposes a series of small modifications to update, clarify, and align OPTN KPD policy. These modifications are expanded upon below, and include changes to OPTN KPDPP administrative policies, informed consent policies for both KPD donors and candidates, and other minor language updates.

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<sup>2</sup> As a pilot, the OPTN KPDPP was governed by the official Operational Guidelines developed by the KPD Workgroup. These Operational Guidelines were not subject to the public comment process, and so allowed the KPD Workgroup the flexibility to adjust the rules and processes of the pilot program as necessary. In 2012, the KPD Workgroup began the process of revising and moving the KPDPP Operational Guidelines to OPTN Policy, in an effort to transition the program out of its pilot stage. The Operational Guidelines were revised a total of 10 times before their ultimate removal in October 2021, at the October 8, 2021 meeting of the OPTN Kidney Transplantation Committee.

<sup>3</sup>OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2021.

[https://optn.transplant.hrsa.gov/media/4hzlnxhy/20211008\\_kidney\\_meeting\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4hzlnxhy/20211008_kidney_meeting_summary.pdf)

## Administrative Updates

The Committee proposes modifications to OPTN administrative policies for the OPTN KPDP, including updates to match offer review deadlines and the deadline extension request process. These updates will bring KPD offer timelines into alignment with current practices, improving the efficiency and success of the OPTN KPDP.

The Committee proposes the following condensed match offer and exchange deadlines:

- Each transplant hospital receiving a match offer must report to the OPTN a preliminary response within two business days of receiving the match offer, as is required by current OPTN policy
- The matched candidate's transplant hospital and the matched donor's transplant hospital 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 of receiving the match offer, shortened from the current deadline of four business days
- The matched donor's transplant hospital must report to the OPTN 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 of receiving the match offer, shortened from four business days
- The matched 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 of receiving the match offer, shortened from 15 business days

These condensed deadlines align with current practices and information sharing capabilities, and will improve the overall efficiency of the OPTN KPDP by establishing shorter exchange timelines.<sup>4,5</sup> The Workgroup considered shortening the deadline for preliminary match offer response, and determined that the current two business days was still an appropriate timeframe, with consideration for smaller KPD programs with limited staffing.<sup>6</sup>

The Committee proposes two new deadlines for paired donor recovery and candidate transplant, which do not exist in current policy:

- The matched donor's transplant hospital must recover the kidney from the matched donor within 60 calendar days of receiving the match offer
- The matched candidate's transplant hospital must transplant the matched donor kidney into the matched candidate within 60 calendar days of receiving the match offer

The shortened offer review deadlines, along with the proposed recovery and transplant deadlines, establish a more efficient timeframe for KPD exchanges and will potentially improve the success of the

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<sup>4</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022. <https://optn.transplant.hrsa.gov/media/tcol2qx5/220220418-kpd-summary.pdf>

<sup>5</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022. <https://optn.transplant.hrsa.gov/media/vxblcj/20220202-kpd-administrative-focus-group-summary.pdf>

<sup>6</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022. <https://optn.transplant.hrsa.gov/media/aapn15jx/220220516-kpd-summary.pdf>

KPD program.<sup>7</sup> This will help reduce the time between match offer and transplant, which in turn reduces the risk of an exchange breaking due to issues such as candidate illness or donor unavailability.<sup>8,9</sup>

These deadline modifications were informed by experiential evidence of the Workgroup, which include members from participant programs in the OPTN KPDPP, with feedback from both the OPTN Transplant Coordinators (TCC) and Transplant Administrators Committees (TAC). Members emphasized that longer times from match run to transplant increase the risk that a donor or candidate issue develops, such as pregnancy, loss of employment, health insurance changes, or illness, which can prevent the fulfillment of the chain or exchange.<sup>10</sup>

Match refusal data from 2016 through 2021 (**Figure 1**) supported these concerns; donor-related, candidate-related, and 'other' refusal reasons were the leading reasons for all match refusals submitted after 15 business days from time of match offer.<sup>11,12</sup>

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<sup>7</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

<sup>8</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022.

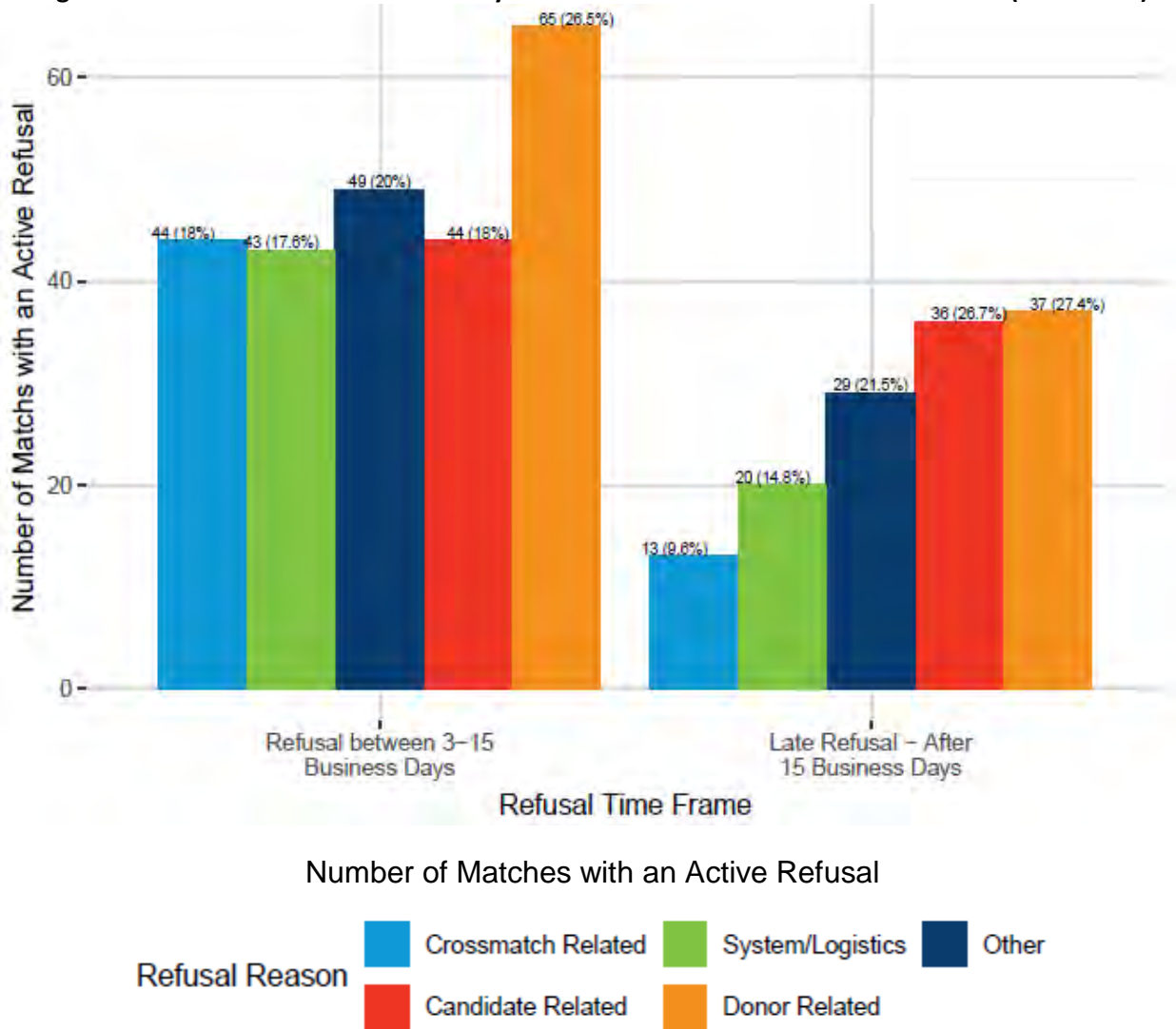
<sup>9</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022. <https://optn.transplant.hrsa.gov/media/nakovbke/20220617-kpd-summary.pdf>

<sup>10</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

<sup>11</sup> Analysis of OPTN KPDPP Match Refusal Data from 2016-2021, presented to the Workgroup on June 17, 2022.

<sup>12</sup> Between 2016 and the end of 2021, 25 percent of offers refused after the preliminary response deadline occurred at least 31 days from time of match offer, and 11 percent occurred 60 days or more from time of match offer.

**Figure 1: KPDP Match Offer Refusals by Time Frame of Refusal and Refusal Reason (2016-2021)**



Donor and candidate-related refusal categories include reasons such as:

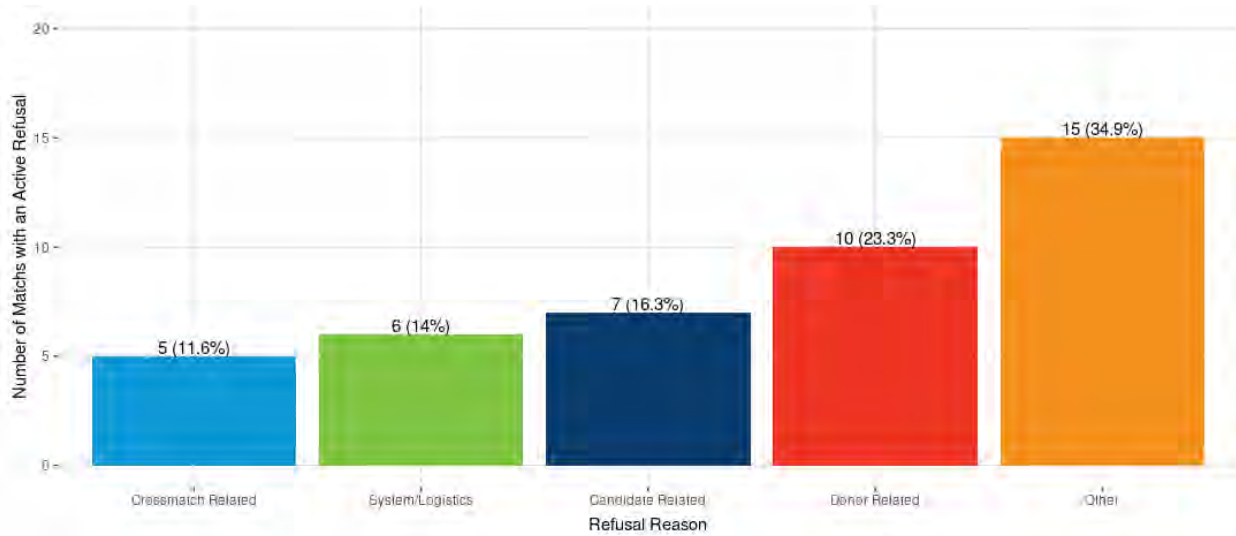
- Patient illness, unavailability, or temporary unsuitability
- Candidate already transplanted, transplant in progress, or other offer being considered
- Candidate involved in pending exchange with another KPD program
- Donor unavailability, including donor pregnancy, donor travel, etc.
- Patient death

In a few cases, donors refused to donate on the exchange timeline, citing that the match timing was too long.<sup>13</sup>

<sup>13</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

Of note, systems and logistics-related refusal reasons remained relatively low, accounting for only 6 of all refusals submitted after 60 calendar days, as shown in **Figure 2**.<sup>14</sup>

**Figure 2: OPTN KPDPP Match Offer Refusals Submitted After 60 Calendar Days by Refusal Reason (2016 – 2021)**



After reviewing this data, the Workgroup achieved consensus in support of the condensed offer review deadlines and the proposed transplant and recovery deadlines, reiterating the reduced transplant and recovery timelines will reduce the risk of a match run failing due to donor and candidate issues as revealed in the data.<sup>15,16</sup> Furthermore, the low frequency of systems and logistics related refusal reasons after 60 days indicates that a 60 day timeframe between match offer and transplant and recovery should not pose logistical challenges to OPTN KPDPP programs. The Workgroup and members of the TCC and TAC also noted the OPTN KPDPP’s extension request process, which allows programs to request extended deadlines where necessary.<sup>17</sup>

Current policy regarding extension requests specifies that an extension request is automatically denied and the exchange terminated if any of the hospitals in the exchange fails to respond to the extension request within the allotted timeframe.<sup>18</sup> The Workgroup acknowledged that a hospital may not submit a response for any number of reasons, particularly smaller programs with limited KPD staff.<sup>19</sup> The Workgroup emphasized that termination of an exchange due to administrative process failures was unfair to the patients in the exchange, and recommended that a non-response by any transplant hospital in the exchange default to an approval of the extension request.<sup>20</sup> The Committee proposes modifying this policy, such that the extension is granted if any of the transplant hospitals in the

<sup>14</sup> Analysis of OPTN KPDPP Match Refusal Data from 2016-2021.

<sup>15</sup> Analysis of OPTN KPDPP Match Refusal Data from 2016-2021, presented to the Workgroup on June 17, 2022.

<sup>16</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

<sup>17</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022

<sup>18</sup> OPTN Policy 13.11.A: Requesting a Deadline Extension for a KPD Exchange

<sup>19</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

<sup>20</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022.

exchange fail to respond. This update will both increase fairness to patients and prevent the termination of an exchange due to non-response.<sup>21</sup>

The Workgroup also discussed the match offer review requirements, including required donor information sharing with the matched candidate's transplant hospital. The Workgroup considered specifying certain donor information to be made available, particularly renal images. Renal images are critical to offer evaluation, as they provide necessary information regarding organ anatomy. The Workgroup also considered requiring renal images and other pertinent donor information to be made available upon offer receipt. The Workgroup noted that specifying required donor information could streamline donor information sharing, and decided to request community input.<sup>22</sup>

The Committee seeks feedback on the following questions, including questions on specification of shared donor information requirements:

- Do the deadlines provide sufficient time to perform the required tasks and review the match offer? Is the 60 day deadline from time of match offer to recovery and transplant surgery appropriate?
- Should the deadline for the provision of a preliminary response be shortened to one business day from receipt of match offer, or is two business days more appropriate? If so, why?
- Should clinical donor information, such as renal images, be specified as required donor information made accessible to the matched candidate's transplant hospital within the three business day deadline? If so, why?
- Should the donor's entire evaluation record, including renal images, be made available in the OPTN KPD System at time of match offer? If so, what is the rationale?

## Informed Consent

The Committee proposes several modifications to informed consent policies for KPD participants, including *OPTN Policy 13.3: Informed Consent to KPD Candidates* and *OPTN Policy 13.4: Informed Consent for KPD Donors*. These updates will provide clarity on applicable patient populations and ensure appropriate, holistic informed consent. One such modification includes clarification language in informed consent policies for KPD donors and candidates that these requirements apply to donors and candidates participating in any KPD program.

Current informed consent policy for KPD donors requires that transplant programs inform potential paired donors of "the possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital." The Workgroup felt that this language was not inclusive enough of overall financial risk to living donation, and that financial risk conversations should also include education on potential resources available to defray costs related to living donation, such as the National Living Donor Assistance Center.<sup>23</sup> Though it is rare for paired donors to travel to the matched recipient, the Workgroup acknowledged the nuance of travel costs in regards to living donation in a KPD program.<sup>24</sup> The Committee proposes alignment of financial risk

<sup>21</sup> Ibid.

<sup>22</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

<sup>23</sup> National Living Donor Assistance Center. <https://www.livingdonorassistance.org/>

<sup>24</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022. <https://optn.transplant.hrsa.gov/media/y30g3sq5/20211213-kpd-meeting-summary.pdf>



language for informed consent for KPD donors with that in *OPTN Living Donation Policy 14.3: Informed Consent Requirements*. This alignment expands informed consent requirements for KPD donors to be more inclusive of financial risks and to ensure KPD donors are informed of resources potentially available to mitigate donation related costs.<sup>25</sup>

The Committee also proposes an additional update to informed consent requirements for KPD donors, to require that the transplant hospital obtain the paired 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.<sup>26</sup> This update clarifies language regarding the paired donor's right to withdraw and aligns informed consent documentation requirements with those in *OPTN Living Donation Policy 14.3: Informed Consent Requirements*.<sup>27, 28</sup>

## Bridge Donors

KPD Chains can be initiated by unpaired, non-directed living donors. In these cases, the candidate at the end of the chain is matched while their donor becomes an "Exchange Ending Donor." Exchange ending donors will either initiate a new KPD chain as a bridge donor in a future match run, or donate to a candidate on the deceased donor waitlist. In discussing OPTN policies regarding bridge donors, the Workgroup found the current definition of bridge donor to be unclear and potentially confusing.<sup>29</sup> The Workgroup felt it was appropriate to update the definition of Bridge Donor as shown in *OPTN Policy 1.2: Definitions*, to reflect these options. The Committee proposes the following definition of Bridge Donor, which is inclusive of all options available to a Bridge Donor:

### **Bridge Donor**

A KPD donor at the end of a KPD chain who will be in future match runs.

Currently, *OPTN Policy 13.4.E: Additional Requirements for Bridge Donors* provides additional informed consent requirements for Bridge Donors, due to their unique circumstance. These requirements include providing an estimate of how long a bridge donor can expect to wait before undergoing surgery to recover their kidney, based on the experience of the transplant hospital. The bridge donor has the option to revise the amount of time they are willing to be a bridge donor based on this estimate, and the transplant hospital must maintain documentation of how long a bridge donor is willing to be a bridge donor. In discussing this requirement, the Workgroup noted that accurate estimates are difficult to obtain and can vary, particularly due to donor factors such as blood type and human leukocyte antigen (HLA) typing.<sup>30</sup> The Workgroup iterated that the most influential and important factor in how long a donor can expect to wait is how long the bridge donor is willing to wait.<sup>31</sup> Acknowledging this, the Committee proposes removing the requirement to provide an estimate, and instead including language emphasizing the bridge donor's autonomy in determining and revising how long they are willing to wait. Transplant hospitals will still be required to document in the donor's medical record how long the donor is willing to be a bridge donor, and any revisions to how long the donor is willing to be a bridge donor. This policy will ensure both bridge donor autonomy and that the transplant program has explicit

<sup>25</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022

<sup>26</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>27</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022

<sup>28</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>29</sup> *Ibid.*

<sup>30</sup> *Ibid.*

<sup>31</sup> *Ibid.*

conversations with the bridge donor regarding expectations.<sup>32</sup> The Workgroup discussed including a requirement for the transplant program to obtain the bridge donor's signature confirming that the bridge donor has been informed that they may determine how long they are willing to be a bridge donor, and that they may revise that estimate. Ultimately, the Workgroup determined that a signature would not necessarily be appropriate, as bridge donors may continue to revise how long they are willing to be a bridge donor.<sup>33</sup> The Committee seeks feedback from the community on whether a requirement to obtain the bridge donor's signature confirming this specific informed consent is appropriate.

## Additional Clarifications and Alignments

The Committee proposes modifications to non-directed donor requirements in both KPD and Living Donor policy. These modifications include minor updates to *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors*, to specify these requirements apply to non-directed donor participants in any KPD program and to remove reference to the donor's donation service area, which is no longer relevant.<sup>34</sup> The Committee also proposes the inclusion of a cross reference in *OPTN Policy 14.6.B: Placement of Non-Directed Living Donor Organs*, which notes these requirements do not apply to non-directed donors participating in a KPD program. The cross reference will clarify that non-directed living kidney donors participating in a KPD program are subject to *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors*.<sup>35</sup>

The Committee also proposes minor language updates to *OPTN Policy 13.7.G: OPTN KPD Waiting Time Reinstatement*, to align with general OPTN policy regarding immediate and permanent non-function of a transplanted kidney.<sup>36</sup>

## NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) directed the OPTN to exercise oversight over living donation.<sup>37</sup> Under 42 CFR 121.4(a)(6), the Secretary directed the OPTN "to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule."<sup>38</sup> Furthermore, Congress modified NOTA in 2007 to permit human organ paired donation under the law,<sup>39</sup> and the current OPTN Contract requires the Contractor to "maintain KPDPP policies and develop new policies."<sup>40</sup> This project addresses living organ donors and candidates enrolled in kidney paired donation programs, including the KPDPP, by updating kidney-paired donation policy.

<sup>32</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, February 28, 2022.

<https://optn.transplant.hrsa.gov/media/bbkbm4wd/20220228-kpd-summary.pdf>

<sup>33</sup> *Ibid.*

<sup>34</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022.

<sup>35</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022.

<sup>36</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022.

<sup>37</sup> Department of Health and Human Services, Health Resources and Services Administration, "Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines," 71 Fed. Reg. 34946 No. 116 (June 16, 2006).

<https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-and-transplantation-network-optn-living-donor> (accessed June 23, 2020).

<sup>38</sup> *Ibid.*

<sup>39</sup> 42 USC §274e

<sup>40</sup> Organ Procurement and Transplantation Network; HHS250201900001C, Performance Work Statement Task 3.4.3: Operate the OPTN Kidney Paired Donation Pilot Project (KPDPP)

## Implementation Considerations

### Member and OPTN Operations

#### *Operations affecting Transplant Hospitals*

This proposal is expected to impact 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 proposal also 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.

#### *Operations affecting Histocompatibility Laboratories*

This proposal 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.

#### *Operations affecting Organ Procurement Organizations*

This proposal is not anticipated to affect the operations of organ procurement organizations.

#### *Operations affecting the OPTN*

This proposal will not require information technology implementation. OPTN Policy will be updated, and a policy notice sent out to members. Current educational offerings for participating transplant programs will be updated appropriately.

## Potential Impact on Select Patient Populations

The expanded and clarified informed consent requirements will positively impact living kidney donor and kidney candidate participants in all KPD programs, with expanded and clarified informed consent requirements. The requirement to inform living donor participants in KPD programs of potential resources available to defray donation-related costs, as well as expanded specification of financial risk, will particularly benefit living donor participants in all KPD program. The proposed policy changes will have the greatest positive impact on participants in the OPTN KPDPP, who will benefit from improvements to the overall efficiency of the program, due to shortened match offer review deadlines and the addition of deadlines for match offer to transplant and recovery. Participants in the OPTN KPDPP will also benefit from updates to the exception request policy, which prevent the termination of an exchange due to administrative lapse.

## Projected Fiscal Impact

### *Projected Impact on Histocompatibility Laboratories*

There is expected to be minimal fiscal impact for histocompatibility laboratories, mainly related to training, and no expected ongoing costs.

### *Projected Impact on Transplant Hospitals*

There is no expected fiscal impact for transplant hospitals.

### *Projected Impact on the OPTN*

This proposal will not require any information technology changes, but will involve standard educational and communication efforts.

### *Projected Impact on Organ Procurement Organizations*

There is no expected fiscal impact for organ procurement organizations.

## Post-implementation Monitoring

### Member Compliance

The OPTN will continue to review the KPD requirements as outlined in policy. Site surveyors will also review a sample of KPD donor medical records for a document signed by the paired donor confirming that the paired donor has been informed that the paired donor may withdraw from participation in the KPD program at any time, for any reason.

### Policy Evaluation

This policy will be formally evaluated approximately 1 year and 2 years post implementation. The following metrics will be evaluated as OPTN KPDPP data become available and compare pre- and post-policy implementation cohorts:

- Median time from match run to transplant
- Numbers and percentages of initially accepted match offers that requested an extension of deadlines for evaluations post-match outlined in policy proposal *Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer*
- Count of reasons for requested extension of deadlines for evaluations post-match outlined in policy proposal *Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer*

## Conclusion

The OPTN Kidney Transplantation Committee proposes a series of minor modifications to OPTN KPD policy to provide clarity, align policy language with other OPTN policies, and improve efficiency of the KPD program.

The proposed modifications will condense match offer and evaluation deadlines, bringing them up to date with current practices. This will shorten the time between match offer and transplant, which in turn will reduce the risk of chain breakage due to issues such as candidate illness or donor unavailability. Additional adjustments to administrative policies are proposed, to improve fairness to patients and prevent termination of exchanges due to administrative lapses. These administrative policy updates will improve the efficiency of the KPDPP and may increase the success of KPDPP, with reduced risk of exchange breakage or termination.

The Committee also proposes updates to several informed consent policies for both candidate and donor KPD participants, to provide clarity, emphasize donor autonomy, and align requirements with those in OPTN Living Donor Policy. These changes include expanded language regarding financial risk and potential resources available to defray donation related costs. Informed consent requirements for bridge donors will also be modified, to underscore donor autonomy in determining how long a bridge donor is willing to wait and ensure transplant programs maintain documentation of donor decisions.

## Considerations for the Community

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

1. Do the deadlines provide sufficient time to perform the required tasks and review the match offer? Is the 60 day deadline from time of match offer to recovery and transplant surgery appropriate?
2. Should the deadline for the provision of a preliminary response be shortened to one business day from receipt of match offer, or is two business days more appropriate? If so, why?
3. How can overuse of extension requests be discouraged? How can better performance be incentivized in the program?
4. Should clinical donor information, such as renal images, be specified as required donor information made accessible to the matched candidate's transplant hospital within the three business day deadline? If so, why?
5. Should the donor's entire evaluation record, including renal images, be made available in the OPTN KPD System at time of match offer? If so, what is the rationale?
6. Should policy specify that transplant programs obtain a signature from bridge donors confirming informed consent and the estimated period of willingness to be a bridge donor? If so, why?

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 1.2 Definitions

#### 2 **Bridge donor**

3 A Kidney Paired Donation (KPD) donor ~~who does not have a match identified during the same match run~~  
4 ~~as the donor's paired candidate and continues a chain in a future match run~~ at the end of a KPD Chain  
5 who will be in future match runs.  
6

### 7 13.3 Informed Consent for KPD Candidates

8 The below requirements apply to candidates participating in any KPD program. (Leads into subsections)  
9

### 10 13.4 Informed Consent for KPD Donors

11 The below requirements apply to donors participating in any KPD program. (Leads into subsections)  
12

#### 13 13.4.C *Additional Requirements for KPD Donors*

14 For any KPD exchange, the paired donor's transplant hospital must maintain documentation in  
15 the paired donor's medical record that it has informed the paired donor of *all* of the following:  
16

- 17 1. The KPD program's matching requirements
- 18 2. KPD donors and candidates do not choose their match
- 19 3. A KPD donor or a candidate may decline a match
- 20 4. The possibility of helping more than one candidate receive a transplant
- 21 5. The possibility that the paired donor may have to wait to find a match
- 22 6. The possibility that the paired donor might have to wait longer to donate after a match has  
23 been identified because of logistical issues
- 24 7. The possibility that the paired candidate might not receive a transplant because of an  
25 unexpected issue with the matched donor's kidney found during or after surgery
- 26 8. The possibility that the paired donor's kidney might not be transplanted or the paired  
27 donor's matched candidate might not receive a transplant because of unexpected events
- 28 9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include  
29 any additional priority for the paired candidate on the deceased donor waiting list
- 30 10. ~~The possibility that the matched candidate's insurance might not cover travel costs if the~~  
31 ~~paired donor travels to the matched recipient transplant hospital~~
- 32 11. The possibility that personal expenses of travel, housing, child care costs, and lost wages  
33 related to donation might not be reimbursed; however, resources might be available to  
34 defray some donation related costs.
- 35 12. The possibility that the paired donor's paired recipient and the paired donor's matched  
36 recipient might not have equal outcomes

- 37 13. The possibility of the paired donor’s name appearing on the matched candidate’s insurance
- 38 estimation of benefits
- 39 14. That the donor’s kidney could be lost in transport, and other potentially negative
- 40 consequences related to shipping a kidney
- 41 15. That the paired donor may require additional testing, including multiple blood draws for
- 42 crossmatching
- 43 16. The KPD program’s rules for when members are allowed to facilitate meetings between
- 44 matched donors and recipients
- 45

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

50 **13.4.D Additional Requirements for Non-Directed Donors (NDD) Participants in KPD**  
 51 **Programs**

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

- 55
- 56 1. Participating in KPD
- 57 2. Donating to a candidate waiting for a deceased donor kidney according to *Policy 14.6.B:*
- 58 *Placement of Non-directed Living Donor Organs*
- 59 3. Any other options available ~~in the NDD’s donation service area~~ to the NDD
- 60

61 **13.4.E Additional Requirements for Bridge Donors**

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

- 65
- 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. ~~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.

66



67 The bridge donor’s transplant hospital must maintain documentation in the donor’s medical  
 68 record that the donor has verbally consented to remain a bridge donor each time the donor is  
 69 identified as a bridge donor in an accepted KPD exchange.  
 70

71 **13.7.G OPTN KPD Waiting Time Reinstatement**

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

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

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

86  
 87 KPD waiting time will be reinstated when the OPTN receives a request for reinstatement of KPD  
 88 waiting time and the required supporting documentation from the KPD candidate’s transplant  
 89 hospital.

90 **13.11 ~~Receiving and Accepting KPD Match Offers~~ KPD Match Offer and**  
 91 **Transplant Timing Requirements**

92 Each OPTN KPD program must designate a KPD contact to receive notification of match offers.  
 93  
 94

**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"> <li>• Contents required in the crossmatch kit</li> <li>• Instructions for the donor</li> <li>• Address at which to send the completed blood samples</li> </ul>	4 <u>3</u> business days of receiving the match offer.
The matched donor’s transplant hospital	Report to the OPTN the agreed upon date of the crossmatch	4 <u>3</u> business days of receiving the match offer.



The following members:	Must:	Within:
The matched donor's transplant hospital	Make all of the following matched donor's records accessible to the matched candidate's transplant hospital: <ul style="list-style-type: none"> <li>• Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital</li> <li>• 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></li> <li>• Additional records requested by the matched candidate's transplant hospital</li> </ul>	<del>4</del> <u>3</u> business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN the results of the crossmatch	<del>15</del> <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	<del>15</del> <u>10</u> business days of receiving the match offer.
<u>The matched donor's transplant hospital</u>	<u>Recover the kidney from the matched donor</u>	<u>60 days of receiving the match offer</u>
<u>The matched candidate's transplant hospital</u>	<u>Transplant the matched donor kidney into the matched candidate</u>	<u>60 days of receiving the match offer</u>

95  
 96 If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines  
 97 above, then the exchange will be terminated unless a transplant hospital requests an extension. If a  
 98 transplant hospital submits an extension request before the deadline, the exchange will not terminate  
 99 until the resolution of the extension request or the deadline is reached, whichever comes last.

100  
 101 **13.11.A Requesting a Deadline Extension for a KPD Exchange**

102 The transplant hospital may request an extension for any of the deadlines in *Table 13-4* by  
 103 submitting a request in writing to the OPTN. This written request must include the reason for  
 104 the request and the new requested deadline date. Upon receipt of the request for extension,  
 105 the OPTN will notify all of the transplant hospitals in the exchange. Upon notification, the  
 106 transplant hospitals in the exchange must respond to the request for extension within 2  
 107 business days. If all other transplant hospitals in the exchange agree to the extension, it will be  
 108 granted. If any of the transplant hospitals in the exchange refuse the extension request, the  
 109 extension will not be granted.

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

116  
117 *14.6.B Placement of Non-directed Living Donor Organs*

118 Prior to determining the placement of a non-directed living donor organ, including non-directed organs  
119 from domino donors and non-domino therapeutic organ donors, the recovery hospital must obtain the  
120 match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed  
121 living donor organ is placed, the recovery hospital must document how the organ is placed and the  
122 rationale for placement.

123  
124 This requirement does not apply to non-directed living kidney donors who donate a kidney through a  
125 Kidney Paired Donation (KPD) arrangement. Non-directed living kidney donors who donate a kidney  
126 through a Kidney Paired Donation (KPD) arrangement are subject to Policy 13.4.D: Additional  
127 Requirements for Non-Directed Donors.