

**OPTN Kidney Paired Donation Pilot Program (KPD)
Informed Consent Reference**

Background: In June 2015, the OPTN/UNOS Board of Directors approved informed consent policy that require transplant hospitals to inform KPD candidates and donors of the risks and benefits of participating in a KPD program and the logistics of the KPD program’s matching process. These informed consent requirements apply to all KPD programs. These policy changes became effective on December 1, 2015. Updates to 13.3.C, 13.4.C & 13.7.H (Remedy for failed exchanges) are effective October 24, 2019.

Purpose: This document clarifies information on certain elements of the OPTN Kidney Paired Donation Pilot Program (KPD) so that transplant hospitals that participate in the OPTN KPD can inform candidates and donors appropriately. This document is meant to serve as an informational resource and participating transplant hospitals should consult their legal department for further guidance on informed consent documentation. Evidence of informed consent must be maintained in the donor and candidate medical records.

Please note that in addition to *Policy 13* informed consent requirements, donors and candidates have other informed consent requirements outlined in *Policy 14* and *Policy 3*. Transplant hospitals should refer to these policies to ensure that donors and candidates are properly informed and consent is obtained. For any KPD exchange, the paired donor’s transplant hospital is responsible for obtaining and documenting informed consent from the paired donor according to *Policy 14: Informed Consent Requirements*. If a different transplant hospital performs the organ recovery, the recovery hospital must also obtain and document informed consent according to *Policy 14*.

Informed Consent Element	Informed Consent Reference
<p>Release of Protected Health Information</p> <ul style="list-style-type: none"> • Consult your hospital's legal department regarding your institution’s process for release of health information. • The OPTN will accept one document that provides consent to share information with any and all transplant hospitals to which the candidate is matched within a match run. Language may be added to a hospital's existing release of health information document, or the transplant hospital may create a new document. 	13.3.A & 13.4.A
<p>Shipping Risks</p> <ul style="list-style-type: none"> • Both the donor and the candidate must be informed of the risks of shipping a donor kidney from the donor recovery hospital to the matched candidate’s transplant hospital before the OPTN KPD program will match a donor and candidate from different hospitals. Potentially negative consequences from shipping a kidney may include: <ul style="list-style-type: none"> ○ Possible delay in function of organ due to the extra time it takes to transport a kidney between donor recovery and recipient transplant hospitals. ○ Accidental damage or loss of organ during transportation between donor recovery and recipient transplant hospitals. 	13.3.B & 13.4.C

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<p>Matching Requirements for the OPTN KPD</p> <ul style="list-style-type: none"> • Donors and candidates will be matched using a computer program that maximizes the number of matched pairs while providing additional consideration for specific populations, such as children and highly sensitized recipients. • The computer system does not provide multiple solutions (i.e. set of matches), the computer finds and displays one solution for each match run. • Donors are matched based on donor blood type and antigens compared to candidate blood type and unacceptable antigens. The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types including non-A₁ to O and B candidates and non-A₁B blood types to B candidates. • Donor and candidate choices can be used to identify match opportunities (i.e. distance willing to travel, option to be a bridge donor, etc). However, donors and candidates cannot choose specific individuals or pairs with whom they match. <p>Donors and candidates have the right to decline any match offered at any time in the match process. The candidate transplant hospital determines if the matched donor kidney is appropriate for their recipient.</p> <ul style="list-style-type: none"> • The paired donor may withdraw from participation in the KPD program at any time, for any reason. The paired donor's transplant hospital must obtain the paired donor's signature that confirms the donor has been informed of this. <p>Match run eligibility requirements are outlined in <i>Policy 13.6</i>. Details on specific elements of <i>Policy 13.6</i> and <i>13.7</i> should be made available to donors and candidates upon request.</p>	<p>13.3.C & 13.4.C</p>
<p>Donors</p> <ul style="list-style-type: none"> • Donors may have to wait to find a match. In the OPTN KPD, the length of time varies according to the ABO of both donor and candidate, donor antigens, candidate unacceptable antigens, and characteristics of the existing pool of donors and candidates. In the OPTN KPD, if a paired donor is identified as a bridge donor in a match run they will be matched with a candidate in a different match run than their paired candidate. This may extend the time a donor waits (see additional bridge donor information below). • After a match has been identified, there is a possibility that the paired donor may have to wait an additional amount of time to donate because of logistical issues (i.e. ability to schedule operating rooms for surgery, availability of donors and candidates involved in the exchange, etc.) • The KPD donor may help more than one candidate receive a transplant. In the OPTN KPD match offers can be as short as 2 pairs or they can be chains that begin with a NDD and extend with one or multiple bridge donors. • Many matches are terminated prior to donation and transplantation. Donors may need to supply multiple blood samples on multiple occasions to crossmatch against candidates in different matches. 	<p>13.4.C</p>

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<ul style="list-style-type: none"> • It is possible that personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources such as the National Living Donor Assistance Center (NLDAC) might be available to defray some donation related costs. • The paired donor's name may appear on the matched candidate's insurance estimation of benefits • The donor's paired and matched recipient might not have equal outcomes 	
<p>Non-Directed Donors (NDD's) When a NDD presents at a transplant hospital, the hospital must inform the NDD of all options for donation in their Designated Service Area (DSA) including but not limited to:</p> <ul style="list-style-type: none"> • Participating in one or multiple KPD programs • Donating directly to the waitlist according to <i>Policy 14.7.B: Placement of Non-directed Living Donor Kidneys</i> • Any other options available to the NDD. 	13.4.D
<p>Bridge Donors Each paired donor, at the discretion of the donor hospital, can be given the option of bridge donation at the time they enter KPD. Before agreeing to bridge donation, the donor must be informed of when a chain will end with a bridge donor.</p> <p>In the OPTN KPD, a chain will end with a bridge donor if the following conditions are met:</p> <ul style="list-style-type: none"> • The chain begins with a NDD or has been extended with another bridge donor • The hospital who entered the NDD chooses to extend the chain with a bridge donor • The paired donor agrees to be a bridge donor • The paired donor hospital agrees for the paired donor to be a bridge donor <p>If one of more of these conditions are not met, the last donor in the chain will be offered to the deceased donor waiting list at the hospital that entered the NDD. The transplant hospital must document that the donor verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted exchange (other options would be donate to waitlist or decline to donate).</p> <p>The amount of time a bridge donor waits before a match is found and undergoes surgery is primarily based on the ease or difficulty in matching the bridge donor's blood type and antigens with candidates in the pool. Generally speaking:</p> <ul style="list-style-type: none"> ○ Blood type O donors match immediately ○ Blood type A and AB donors may take several months or longer to match. ○ Blood type B donors are somewhere in between. • The bridge donor determines the amount of time the donor is willing to be a bridge donor. Bridge donors have the option to revise 	13.4.E

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<p>the amount of time they are willing be a bridge donor. The bridge donor’s transplant hospital must 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 transplant hospital must document that revision in the donor’s medical record.</p> <ul style="list-style-type: none"> • Bridge donors may be waiting for a match long enough that their medical evaluation expires per transplant hospital policy. In that case, they would require additional evaluation prior to donor nephrectomy. • Many matches are terminated prior to donation and transplantation. Bridge donors may need to supply multiple blood samples on multiple occasions to crossmatch against candidates in different matches. • The bridge donor may decline to donate at any time, for any reason • All of the bridge donor’s options for donation, including: <ul style="list-style-type: none"> • Continued participation as a bridge donor in the KPD program • Donation to a candidate waiting for a deceased donor kidney • Any other options available to the bridge donor 	
<p>Unexpected Events Preventing Donation or Recipient Transplantation</p> <p>Unexpected events may occur that prevent the paired donor’s kidney from being transplanted or cause a failed exchange. A failed exchange is when a donor donates but their paired candidate does not receive a transplant. Unexpected events that might prevent donation or recipient transplantation include but are not limited to the following examples:</p> <ul style="list-style-type: none"> • A candidate might not receive a transplant because of an unexpected issue with the matched donor’s kidney found during or after surgery. • An event may occur in the operating room that makes it necessary to stop a donor procedure. In this case, one recipient would not receive a kidney. In the OPTN KPD, if a donor or recipient surgery has begun, this surgery will continue even if another surgery in the match must stop. • If it is necessary to stop a recipient surgery, a kidney would be available. This kidney would be given to a recipient on the deceased donor waiting list according to <i>Policy 8</i>. 	13.3.C & 13.4.C

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<p>Remedy for Failed Exchanges</p> <ul style="list-style-type: none"> • A KPD candidate who does not receive a kidney transplant from the matched donor <i>for any reason</i> after the candidate's paired donor has donated is considered an orphan candidate. • A candidate will be eligible for orphan candidate priority <i>only</i> if the candidate qualified for orphan status through participation in the OPTN KPD program. • An orphan candidate will receive 1,000,000 priority points, even if the candidate has another willing living donor. The orphan candidate will retain this priority until the orphan candidate receives a kidney transplant. The orphan candidate can always refuse a match offer and retain orphan candidate priority. • This priority will ensure the orphan candidate receives a match offer <i>if</i> the candidate matches to either a non-directed donor or bridge donor in the system, but does not guarantee that the candidate will match any donor. • There is no additional priority on the deceased donor waiting list for any candidate involved in a failed exchange in any KPD program. 	<p>13.3.C & 13.4.C & 13.7.H</p>
<p>Communication Between Donors & Recipients Each transplant hospital must inform donors and candidates of their hospital specific policy regarding communication between matched donors and candidates. Requirements for this policy are listed in <i>Policy 13.12: Communication between KPD Donors and Recipients</i>.</p>	<p>13.3.C & 13.4.C</p>