At-a-Glance

Proposal for Informed Consent for Kidney Paired Donation

- **Affected/Proposed Policies:** Policies 13.3 (Informed Consent for Candidates); 13.4 (Informed Consent for Potential Donors); 13.6.A (Requirements for Match Run Eligibility for Candidates); and 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

- **Kidney Transplantation Committee**

  The *Proposal for Informed Consent for Kidney Paired Donation* proposes required elements for informed consent for paired candidates and donors participating in any KPD program. The proposal requires transplant programs registering the paired candidates and donors to inform KPD participants of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process, including prioritization information and consequences of shipping kidneys. It also includes additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in Policy 14.3: Informed Consent Requirements.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Transplant Social Workers
  KPD Candidates
  Living Donors

- **Number of Potential Candidates Affected**
  This proposal will affect all candidates and donors participating in any KPD program. There are many other KPD programs across the United States, including the National Kidney Registry (NKR), the Alliance for Paired Donation (APD), and many regional and intra-hospital exchange programs. In the OPTN/UNOS KPDPP alone, as of June 26, 2014 approximately 250 eligible pairs participate in every KPD match run. Through June 30, 2014, NKR reported 1200 people in its cumulative paired patient pool and 350 currently active donors[1], while over 1,000 people have entered the KPDPP patient pool since its inception.[2] Candidates and donors may be registered in more than one KPD program.

- **Compliance with OPTN Strategic Plan and Final Rule**
  OPTN Strategic Plan Goal 4: Promote transplant patient safety
  OPTN Strategic Plan Goal 5: Promote living donor safety

[1] National Kidney Registry, "Paired Exchange Results Quarterly Results as of June 30th, 2014." Accessed on August 27, 2014. http://www.kidneyregistry.org/pages/p302/2_14.php

[2] "The State of the OPTN/UNOS KPD Pilot Program." Accessed on September 4, 2014. http://optn.transplant.hrsa.gov/ContentDocuments/KPD_Report.pdf

Proposal for Informed Consent for Kidney Paired Donation

Affected/Proposed Policy: Policies 13.3 (Informed Consent for Candidates); 13.4 (Informed Consent for Potential Donors); 13.6.A (Requirements for Match Run Eligibility for Candidates); and 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

Kidney Transplantation Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

The *Proposal for Informed Consent for Kidney Paired Donation* proposes required elements for informed consent for paired candidates and donors participating in any KPD program. The proposal requires transplant programs registering the paired candidates and donors to inform KPD participants of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process, including prioritization information and consequences of shipping kidneys. It also includes additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in Policy 14.3: Informed Consent Requirements.

Background and Significance of the Proposal:

In March 2012, the Kidney Transplantation Committee (Kidney Committee) distributed for public comment the *Proposal to Establish Kidney Paired Donation (KPD) Policy*. The proposal included sections regarding informed consent, particularly sections 13.3 (Informed Consent for Candidates) and 13.4 (Informed Consent for Potential Donors).

Themes suggesting ways to improve the proposal before it became policy emerged from public comment, particularly regarding the informed consent sections of the proposal:

- "Modify Policy 13.4 so that it is clear who is responsible for informed consent from potential donors…" (Region 2)
- "…an element of informed consent is missing, namely understanding of the possibility that the donor could serve as a bridge donor, and the potential consequences thereof." (National Kidney Foundation).
- "…whenever possible all elements of the proposals (13.2, 13.3, 13.4) should mirror and should reference rather than duplicate requirements in [Living Donor policy]." (Living Donor Committee).

Joint Societies Work Group

After reviewing the public comment feedback submitted by the public at large, other OPTN/UNOS Committees and OPTN/UNOS regions, the Kidney Committee decided to remove the informed consent sections from the KPD policy proposal that was ultimately approved by the Board of Directors in November 2012. Additionally, the American Transplant Society (AST) and the American Society of Transplant Surgeons (ASTS) notified the KPD Work Group of their desire to discuss the informed consent sections of the proposed policy through a Joint Societies Policy Working Group (JSWG).

Based on the process established by the Rockville Policy Development Discussion, representatives from the Kidney Committee, AST, ASTS, and the North American Transplant

Coordinators Organization (NATCO) formed a JSWG in December 2012. The JSWG was charged to "provide recommendations to OPTN/UNOS regarding the development of informed consent policies for paired donors, candidates and non-directed donors entering the OPTN/UNOS KPD program. The KPD JSWG should provide recommendations regarding the risks and benefits of participating in the KPD program, the KPD matching process, and confidentiality and sharing of protected health information. The KPD informed consent policies are being developed in addition to existing informed consent policies that already apply to all candidates and living donors."

Using the policy language that was distributed for public comment in March 2012 as the starting point, the JSWG carried out its charge over a series of teleconferences spanning from January 2013 to October 2013. In October 2013, the JSWG finalized its recommendations and sent them to the Joint Societies Steering Committee for approval. The Joint Societies Steering Committee reviewed the JSWG recommendations, and ultimately approved them without modification in March 2014. The OPTN/UNOS KPD Work Group subsequently reviewed the JSWG proposal on April 25, 2014 and recommended that the Kidney Committee also approve it without modification.

The structure and content of the JSWG proposal was largely the same as the March 2012 proposal, with some notable modifications: 1) scope; 2) prioritization for candidates in a failed exchange; 3) bridge donor consent; 4) risks of shipping kidneys; and 5) provide donors with matched candidate's transplant hospital outcomes.

1. Scope

First, the JSWG recommended expanding the scope of informed consent policy to apply to all KPD programs. The JWSG held numerous discussions regarding the scope of KPD informed consent policies. OPTN/UNOS Policy 14: Living Donation applies to all living donors. The JSWG members considered of Policy 13: Kidney Paired Donation as a supplement to Policy 14, and therefore proposed that Policies 13.3 and 13.4 apply to all KPD programs.

The Kidney Committee agreed that the scope of KPD informed consent should be broadened to apply to transplant hospitals enrolling donors and candidates in any KPD program. The Kidney Committee clarified that these policies also apply to intra-hospital exchanges. As defined by OPTN/UNOS policy, an exchange is "a set of KPD matches that form a chain, a two-way exchange, or a three-way exchange." Furthermore, the only aspect of the proposed informed consent requirements that is not relevant to intra-hospital exchanges – shipping kidneys – is a minor piece of the entire informed consent process and would be difficult to remove for individual situations. Therefore, the Kidney Committee proposes that all of the KPD informed consent policies included in this proposal apply to transplant hospitals enrolling participants in <u>any</u> KPD program, including non-OPTN KPD programs and intra-hospital paired exchanges.

2. Prioritization for Candidates in Failed Exchange

The JSWG recommended each KPD program prioritize candidates in the event of a failed exchange, in which a paired donor donates but the paired candidate does not receive a kidney from their matched donor due to certain unforeseen circumstances. The JSWG acknowledged that prioritization differs by KPD program, but believed that a candidate in this circumstance should receive prioritization in the KPD program's matching system. Therefore, the JSWG used language that could broadly apply to all KPD programs, but did not specify a precise prioritization for the candidate in any program, only that the candidate be prioritized in some way.

The JSWG recommendation for remedying a candidate involved in a failed exchange included the requirement that the candidate be prioritized in the KPD program in which the exchange failed. The Kidney Committee believed this requirement to be too prescriptive, as it would have required all KPD programs to prioritize these candidates in some way. Instead, the Kidney Committee proposes requiring that transplant programs enrolling a candidate or donor in a KPD program advise the participant of that KPD program's remedy in the event of a failed exchange, or advise the participant that the KPD program does not have a remedy in the event of a failed exchange. If the transplant program is enrolling the paired donor or candidate in more than one KPD program, it must advise the donor and candidate of each KPD program's policies regarding prioritization of candidates subsequent to a failed exchange.

3. Bridge Donor Consent

The JSWG recommended removing the requirement that a bridge donor must verbally consent to continue as a bridge donor every three months, and instead suggested permitting the bridge donor to assert the amount of time he or she is willing to wait. The March 2012 proposal required bridge donors to consent on multiple occasions: before the transplant hospital reported that the donor was willing to be a bridge donor; every three months after the match run in which the donor has been identified as a bridge donor until the bridge donor donates, declines to be a bridge donor, or declines to donate; and upon identification of a matched recipient.

The JSWG considered three options for informed consent for bridge donors:

- Option 1:
    - No separate consent for a bridge donor at all (the donor already implicitly opted to be a bridge donor when he or she agreed to be a living donor)
- Option 2:
    - The transplant hospital obtains consent from the donor twice. The first consent is obtained when the donor initially agrees to be a bridge donor. The donor would be informed how the chain ends, and be provided an estimated amount of time for when the chain would be complete, so the bridge donor would not be "on call" for an indefinite amount of time. The second consent is obtained upon identification of a match.
- Option 3:
    - The transplant hospital obtains informed consent when the donor initially agrees to be a bridge donor, and subsequently at different intervals while the hospital is looking for a match for the bridge donor. The intervals would be different than the originally proposed three month intervals, and the chain could therefore remain open without giving the bridge donor an expected timeframe.

The JSWG engaged in many discussions regarding whether consent on multiple occasions is necessary for bridge donors. Some members believed that a donor's initial consent to be a bridge donor served as their consent. Others believed that obtaining informed consent on various occasions helped protect the donor's freedom to opt out of the donation process, and prevent the donor from being "on call" for an indefinite period of time. These members argued that verbal consent provided the donor the ability to opt out of donation in a non-pressured situation, and that failing to require the transplant hospital to continue to obtain consent could be coercive to the donor. The bridge donors should either have a limited timeframe in which to donate, or they should provide verbal consent at various time points, allowing them to opt out of the donation process.

Ultimately, the JSWG agreed to recommend Option 2, as it struck the appropriate balance between properly informing the donor without the risk of coercing the donor to continue to be a bridge donor longer than he or she truly feels comfortable.

In addition to the other informed consent elements for bridge donors, the JSWG proposal would have required a transplant hospital to obtain verbal consent from the bridge donor each time the donor was identified as a bridge donor in an "accepted match." The Kidney Committee determined that this requirement would be too burdensome, as "accepted matches" do not necessarily result in "accepted exchanges" that proceed to transplantation. The requirement would be difficult for transplant hospitals, and may also translate into donor consent fatigue. The Kidney Committee therefore recommends requiring the transplant hospital to obtain and document verbal consent from the bridge donor upon the event of an "accepted exchange." The Kidney Committee noted this requirement would be far less burdensome, as the bridge donor would already be required to begin the crossmatch process and would therefore be in touch with the transplant hospital.

4. Risks of Shipping Kidneys

The JSWG recommended advising both the paired donor and candidate of the inherent risks in shipping kidneys between transplant centers. The March 2012 proposal only required transplant hospitals to obtain written consent from the candidate to accept a shipped kidney. During discussion, some JSWG members felt this requirement was extraneous, noting such consent is implicit for recipients, as well as the lack of data on loss of living donor kidneys due to shipping. However, an OPTN/UNOS Committee member noted that there is a 1-2% loss of shipped deceased donor kidneys, and it is possible that loss of kidneys from living kidney donation will increase. In addition to obtaining written consent to accept a shipped kidney, the JSWG also recommended requiring the transplant hospital to inform the candidate about potential consequences of shipping a kidney. Therefore, the JSWG included in the proposal the requirement to inform the candidate of the potential for the donor kidney to be lost in transport, and that greater ischemic time could create a greater incidence of delayed graft function or need for dialysis.

The Kidney Committee agreed that both the candidate and the donor should be informed of the risks inherent to shipping kidneys and accepting shipped kidneys. However, the JSWG proposal contained a numbered list of potential consequences. The Kidney Committee determined the transplant hospitals should advise candidates about the risks of shipping or accepting shipped kidneys, but the list would not be prescribed in policy.

5. Provide Donors with Matched Candidate's Transplant Hospital Outcomes

The JSWG considered the following options regarding when to provide the KPD donor with information about the recipient hospital, and what information should be provided:

- Option 1
    - The recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival."
    - When the recipient center becomes known, the recovery hospital must inform the donor of "the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports," including "the recipient hospital's 1-year patient and graft survival" and "notification about all CMS outcome requirements not being met by the recipient hospital."

- Option 2
    - The recovery hospital does not provide any information about outcomes *until* the matched recipient is identified.
    - Upon identification of the matched recipient, the recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival," as well as the "recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports," including "the recipient hospital's 1-year patient and graft survival" and "notification about all CMS outcome requirements not being met by the recipient hospital."
- Option 3
    - The recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival."
    - Transplant hospitals that are not in good standing (either defined by bylaws or policy) are not permitted to participate in KPD.

The JSWG ultimately agreed upon Option 2. It noted that the donor should not bear the burden of asking for information on the matched recipient's hospital. Option 3 would have placed that onus on the potential donor. The JSWG noted that Option 2 aligns most closely with current CMS requirements, making the informed consent process more streamlined for the recovery hospital. Additionally, Option 2 permits the recovery hospital to complete the requirement in one step, rather than requiring the hospital to provide information to the potential donor at two separate times, as required by Option 1.

The JSWG recommendation filled a perceived "gap" in policy related to advising NDDs of the matched candidate's transplant hospital's outcomes "upon identification of the matched candidate" if the recovery hospital and the recipient hospital will not be the same and the recipient hospital is not known. Upon closer review, the Kidney Committee determined that this "gap" is actually already covered by in *Policy 14*: *Table 14-1: Required Recipient Outcome and Transplanted Kidney Survival Data*. If the recipient hospital and recovery hospital are not the same and the recipient hospital is not yet known, then it necessarily follows that the recovery hospital cannot provide the donor with the matched candidate's transplant hospital's outcomes. But, the recipient's transplant hospital will be known at some point, and at that moment "the recovery hospital and the recipient hospital will not be the same and the recipient hospital is known." Row two in Table 14-1 would then apply to this situation. Removing this requirement also adheres to the suggestion submitted by ASTS, which stated "Beyond adding another regulatory burden, it can threaten the anonymity of those involved. KPD is meant to expand the pool of organs available for transplantation and we encourage both the JSWG and OPTN [K]idney [C]ommittee to finalize recommendations aligned with the spirit of KPD and not create a regulatory burden that will hinder this growing area." The Kidney Committee therefore decided not to modify Table 14-1.

In addition to the informed consent elements included in this proposal, the Kidney Committee also proposed minor modifications to *Policy 13.6: Matching within the OPTN KPD Program*. These proposed modifications are specific to the OPTN KPD program, and do not apply to any other KPD program. The proposed modifications are intended to clarify policy and ensure that it reflects how the OPTN KPD system currently operates.

On August 4, 2014, the Kidney Committee voted unanimously to approve distributing this proposal for public comment (10 support; 0 oppose; 0 abstentions).

Supporting Evidence and/or Modeling:

A March 2012 Kidney Paired Donation Consensus Conference resulted in recommendations for informed consent for living kidney donors participating in paired donation.[3] The Consensus Conference recommendations are shown in **Figure 1**.

Consensus recommendations for KPD donor evaluation and care
1. All potential NDDs should be informed about KPD as an option prior to initiating evaluation
2. The medical and psychosocial evaluation of an NDD should be guided by the "Evaluation of the Living Kidney Donor – a Consensus Document from the AST/ASTS/ NATCO/UNOS Joint Societies Work Group" recommendations
3. NDDs should undergo preliminary (i.e. screening) assessment by a mental health professional before the medical evaluation is initiated
4. The National Living Donor's Assistance Center should provide travel and lodging expenses to the NDDs
5. In addition to the standard informed consent donor nephrectomy, KPD donor informed consent should include these additional elements: risks and benefits of non-KPD donation options, kidney transport, possible kidney redirection due to unforeseen circumstances, and the inability to provide information about the actual recipient
6. Donor privacy should be strictly protected. Specific consent should be obtained from the donor if their name is released to the press
7. The donor center evaluation processes and procedures at which the donor nephrectomy takes place should be followed
8. All evaluative studies (including anatomic imaging) should be completed before registering a donor in KPD and repeated after 12 months. Anatomical imaging, however, does not need to be routinely repeated

Figure 1: Consensus recommendations for KPD donor evaluation and care

Many of the recommendations are already incorporated into OPTN/UNOS policy, specifically *Policy 14.3: Informed Consent Requirements* (for living donation). As the JSWG, KPD Work Group and Kidney Committee view this proposal as a supplement to Policy 14, the only requirements included in the current proposal are those that directly relate to participation in paired donation. The proposed requirements are harmonious with recommendation #5 in Figure 1, as paired candidates and donors are to be advised of the risks of shipping kidneys, and the potential consequences of participating in paired donation, such as the risk of unforeseen circumstances that do not result in a kidney transplant. The proposal also requires transplant programs to advise candidates and donors of the KPD program's specific rules for when, or if, candidates and donors may meet.

[3] Melcher ML, Blosser CD, Baxter-Lowe LA, Delmonico FL, Gentry SE, Leishman R, Knoll GA, Leffell MS, Leichtman AB, Mast DA, Nickerson PW, Reed EF, Rees MA, Rodrigue JR, Segev DL, Serur D, Tullius SG, Zavala EY, Feng S. "Dynamic Challenges Inhibiting Optimal Adoption of Kidney Paired Donation: Findings of a Consensus Conference." *American Journal of Transplantation*, 13 (2013): 851–860. Accessed on August 29, 2014. doi: 10.1111/ajt.12140

Expected Impact on Living Donors or Living Donation:

This proposal will affect living donors participating in any KPD program as these proposed informed consent requirements will apply to all KPD programs. The impact on living donation should be positive, as the informed consent requirements will ensure that paired donors are fully informed of all risks, benefits and options of agreeing to be a living paired donor.

Expected Impact on Specific Patient Populations:

All KPD donors participating in the OPTN/UNOS KPD Pilot program as well as in any other KPD programs will be affected. In 2013, 350 donors were added to the OPTN KPD Pilot Program and 52 donated a kidney. Also in 2013, among the 5,732 living kidney donor transplants performed in the U.S., 587 were reported as having living donor relationship of "non-biological, unrelated: paired donation."[4]

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal adheres to the OPTN Key Goals to "Promote transplant patient safety" and even more specifically "Promote living donor safety" through Key Goals Objective A: Ensure that all living organ donors consent freely, through the stated strategy "Maintain effective standards for the consent of living donors" trough key initiatives such as adopting new policy for consent of potential living kidney donors, provide training/educational materials on new policies, and collaborate with other organizations to create and promote information for potential living kidney donors.

This proposal ensures that paired donors and candidates are advised of the risks and benefits related to participating in any paired donation program. Paired candidates and donors will be apprised of contingencies specifically related to paired donation, including potential adverse events, and will be protected from donating without risk of coercion. The proposal is a result of a collaboration between the OPTN/UNOS, NATCO, AST and ASTS. Lastly, the OPTN/UNOS will produce effective training and educational materials to advise transplant professionals and participants in KPD of these new informed consent policies.

Plan for Evaluating the Proposal:

Due to the nature of this proposal, there will not be an analytical evaluation.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015. This proposal does not require programming in UNet^{SM}. All transplant hospitals participating in paired donation, either as a recovery hospital or a transplant hospital, must become familiar with the requirements in this

[4] Based on OPTN data as of August 15, 2014.

proposal. Upon implementation, transplant hospitals will be responsible for complying with the informed consent requirements in this proposal.

Communication and Education Plan:

This proposal will continue to be monitored for instructional needs. We may offer an instructional program in summer 2015 that will clarify for members updates to KPD policy and the KPD system. Any instructional methodology will allow a question and answer segment.

Communication & Education Activities

Upon board approval, we will communicate these changes to members and make educational materials available online.

- Policy notice on OPTN website
- OPTN news item(s)
- Article on Inside UNOS
- Presentation at Regional Meetings
- Formal training (if needed, summer of 2015)

Compliance Monitoring:
Members will be expected to consent patients based upon the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Members are required to provide documentation as requested.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

13.3 Informed Consent for KPD Candidates

~~*Reserved*~~

13.3.A Release of Protected Health Information

For any KPD exchange, a paired candidate will not be eligible for a KPD match run until the paired candidate's transplant hospital obtains written consent from the paired candidate to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired candidate's transplant hospital must maintain documentation of this consent in the paired candidate's medical record.

13.3.B Agreement to Accept a Shipped Kidney

The OPTN KPD program will only match a paired candidate with a donor whose recovery will occur at a transplant hospital that is different than the paired candidate's transplant hospital if the paired candidate's transplant hospital has obtained documentation in the candidate's medical record that the candidate is willing to receive a shipped kidney.

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that the candidate has been informed of the potentially negative

consequences related to shipping a kidney, including that the donor's kidney could be lost in transport.

13.3.C Additional Requirements for KPD Candidates

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that it has informed the paired candidate of all the following elements of the KPD program:

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 KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients
5. That even if the candidate's paired donor donates, the paired candidate might not be transplanted.
6. The KPD program's remedy for failed KPD exchanges

The paired candidate's transplant hospital must inform the candidate of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4 Informed Consent for ~~Potential~~KPD Donors

~~*Reserved*~~

13.4.A Release of Protected Health Information (PHI)

For any KPD exchange, a paired donor will not be eligible for a KPD match run until the paired donor's transplant hospital obtains written consent from the paired donor to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired donor's transplant hospital must maintain documentation of this consent in the paired donor's medical record.

13.4.B General KPD Donor Informed Consent

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.

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
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 the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney.
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. 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 inform the paired donor 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)

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 14.7.B: Placement of Non-directed Living Donor Kidneys
3. Any other options available in the NDD's donation service area

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. 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's transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor.

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.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

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

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to ~~KPD Operational Guidelines~~*Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

a. Candidate details, including *all* of the following:
   - Last name
   - First name
   - SSN
   - Date of birth
   - Gender
   - Ethnicity
   - ABO
   - Whether the candidate has signed an agreement to participate in the OPTN KPD program
   - Whether the candidate has signed a release of protected health information
   - Whether the candidate is a prior living donor
   - KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.

b. Candidate choices, including *all* of the following
   - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
   - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
   - Minimum and maximum acceptable donor age
   - Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
   - Maximum acceptable donor BMI
   - Maximum acceptable systolic and diastolic blood pressure
   - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
   - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

~~4. The candidate must have current active status in the OPTN KPD program~~

4. ~~5.~~The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
5. ~~6.~~The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
6. ~~7.~~The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

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

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.4.A: Living Donor Blood type Determination* with the following modifications:

    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
    b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to ~~KPD Operational Guidelines~~*Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information

- Whether the potential KPD donor has signed an informed consent as required in policy
- Whether the potential KPD donor has undergone a medical evaluation as required in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
- Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:
- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance or glomerular filtration rate (GF), date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

~~5. The potential KPD donor must have current active status in the OPTN KPD program~~

5. ~~6.~~The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. ~~7.~~The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reasons for refusing offers
7. ~~8.~~The potential KPD donor must not be in a pending exchange in the OPTN KPD program