

# ***Informed Consent for Kidney Paired Donation (KPD)***

**Sponsoring Committee:**      **Kidney Transplantation  
Committee**

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

**Distributed for Public Comment:**      **September 2014**

**Amended After Public Comment:**      **Yes**

**Effective Date:**      **December 1, 2015**

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## **Problem Statement**

In November 2012, the OPTN/UNOS Board of Directors approved that we include several KPD guidelines in OPTN policy, but the Board withheld some sections, including KPD informed consent guidelines for candidates and donors, for further development.

## **Summary of Changes**

The policy changes require transplant programs that register the paired candidates and donors to inform candidates and donors of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process. These risks and benefits include prioritization information and consequences of shipping kidneys. Other changes include requiring 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*.

## **What Members Need to Do**

All transplant hospitals participating in paired donation, either as a recovery hospital or a transplant hospital, must become familiar with the requirements in this proposal. Once policy is implemented on December 1, 2015, transplant hospitals must comply with the informed consent requirements in this proposal. Members will be expected to inform patients based on 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.

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

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

## **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 and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list

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 and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital
11. The possibility that 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 to 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 (GFR), 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

- d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD Donors*
- ~~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