

**OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Informed Consent Focus Group
Meeting Summary
January 31, 2022
Conference Call**

Peter Kennealey, MD, FACS, Chair

Introduction

The Informed Consent Focus Group (the Focus Group) Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 01/31/2022 to discuss the following agenda items:

1. Welcome and Review of Goals
2. Review of Informed Consent Policies
3. Discussion on Potential Updates
4. Project Timeline and Next Steps

The following is a summary of the Workgroup's discussions.

1. Welcome and Review of Goals

The Informed Consent Focus Group reviewed the goals of the KPD Policy Review project, and objectives for the group's discussions.

Data summary:

The goal of the project is to review existing KPD policy to ensure alignment with other OPTN policies, identify areas in need of clarification, and identify potential items for future Workgroup projects.

The Focus Group will review Informed Consent policies and consult Living Donor and Patient Affairs Committees as needed to identify areas in need of modification and alignment:

- 13.3: Informed Consent for KPD Candidates
- 13.4: Informed Consent for KPD Donors

Summary of discussion:

The Focus Group had no questions or comments.

2. Review of Informed Consent Policies

The Focus Group reviewed the KPD informed consent policies, as well as the living donor informed consent policies.

Data summary:

OPTN Policies 13.3 and 13.4

- 13.3: Informed Consent for KPD Candidates
 - 13.3.A Release of Protected Health Information
 - 13.3.B Agreement to Accept a Shipped Kidney
 - 13.3.C Additional Requirements for KPD Candidates

- 13.4: Informed Consent for KPD Donors
 - 13.4.A Release of Public Health Information (PHI)
 - 13.4.B General KPD Donor Informed Consent
 - 13.4.C Additional Requirements for KPD Donors
 - 13.4.D Additional Requirements for Non-Directed Donors (NDD)
 - 13.4.E Additional Requirements for Bridge Donors

Summary of discussion:

One member remarked that policy *13.3: Informed Consent for KPD Candidates* is very consistent with current practices.

3. Discussion on Potential Updates

The Focus Group discussed potential updates and modifications to the KPD informed consent policies.

Summary of discussion:

The Focus Group agreed KPD informed consent policies for donors and candidates should be clarified that these policies apply for all KPD programs, and not just the OPTN KPD Pilot Program. The Focus Group recommended no additional modifications to *13.3 Informed Consent for KPD Candidates*.

13.4.C Additional Requirements for KPD Donors

One member asked how often paired donors travel. Staff shared that it is rare for paired donors to travel to the matched recipient. A member acknowledged the nuance of 13.4.C, and recommended leaving the language related to travel costs as is, and then align the language in the living donor policy. The member continued that the language in the living donor policies on financial risk is clear, but there are additional nuances in the context of KPD that require clarity, particularly regarding costs related to travel to another transplant hospital. This requirement would ensure the donor's awareness, and allow them to make or seek arrangements for travel. The member noted that this could also potentially influence a matched donor's decision to donate.

One member remarked that the "matched candidate's insurance" language in 13.4.C doesn't seem appropriate. Another member responded that the "matched candidate's insurance" language comes from the idea that the recipient's medical need would allow a donor to qualify, and so financially connect the donor to the recipient's insurance. The member agreed that the "recipient insurance" language may not be necessary. Another member recommended updating the wording to "the matched candidate's resources," to include consideration for National Living Donor Assistance Center. One member recommended simply utilizing the same language from the living donor informed consent policy: "personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs." Staff remarked that this could be brought to the Living Donor Committee for feedback.

One member commented the final sentence of 13.4.C, requiring a transplant hospital to inform the paired donor of their right to withdraw from participation, should be emphasized more. The member noted that a signature requirement should be considered.

13.4.D Additional Requirements for Non-Directed Donors (NDD)

The Focus Group discussed the need for clarification that this policy applies to NDDs entering the OPTN KPD Pilot Program only. A member shared that their interpretation of 13.4.D is that, when educating a NDD, the donor should be informed of all potential donation options, including donating to a candidate on the deceased donor waiting list. Another member agreed. One member remarked that this

requirement should exist in living donor policy as well, for consistency. Staff suggested adding a reference to each of the policies in each section as well, and recommended following up with the Living Donor Committee on this topic.

One member suggested substituting the reference to “donation service area” in 13.4.D for other options in the NDD’s living donor program.

13.4.E Additional Requirements for Bridge Donors

One member remarked that the definition of Bridge Donor in 1.2 is confusing, and that “continues the chain in a future match run” becomes prescriptive, because they can decide to be part of a chain or a swap, or a three-way. The Bridge Donor may also choose to donate to the deceased donor list, which is not uncommon. The member recommended updating the language to “who wishes to continue with the donation process.” Staff also shared “donor at the end of a chain who be in future match runs.” The member agreed.

One member noted that per 13.4.E, number 4, it can be difficult for the transplant program to estimate how the donor has to wait, based on a number of factors, particularly blood type. The member pointed out that the biggest factor is how long the bridge donor is willing to wait. Another member agreed. The member felt that 13.4.E, number 4 ensures that the transplant program has that conversation, and the donors are not taken for granted. One member remarked that the wording of this requirement is tricky, and that the KPD Workgroup has previously spent a lot of time discussing this. The member added that this could be simplified. Staff asked if taking out the requirement of time estimation could be helpful, instead requiring transplant programs to notify the bridge donor that they will have the option of determining how long they want to wait. One member agreed. Another member suggested language that requires the transplant program to document that the conversation was had regarding expected waiting times based on the experience of that program. The member emphasized that the spirit of this policy is requiring explicit conversations with bridge donors on expectations.

4. Project Timeline and Next Steps

The Focus Group reviewed the project timeline and next steps for the KPD policy review project, as well as the policy modification categories used to estimate project size and organize potential KPD policy modification projects.

Upcoming Meeting

TBD

Attendance

- **Workgroup Members**
 - Marian Charlton
 - Vineeta Kumar
- **UNOS Staff**
 - Lindsay Larkin
 - Ruthanne Leishman
 - Meghan Oley
 - Kayla Temple

*Due to technological issues, the full attendance list for the KPD Informed Consent Focus Group on 1/31/2022 could not be recorded.