



Informed Consent for Kidney Paired Donation (KPD)

*Kidney Transplantation Committee
June 2015*

The Problem

- Informed consent for KPD programs does not exist in current OPTN policy
- KPD Consensus Conference (2012) and Joint Societies Working Group (2012-2014) recommended that there should be informed consent elements in policy

Strategic Plan Alignment

Goal 4: Promote Transplant Patient Safety & Goal 5: Promote Living Donor Safety

- Ensure that participants are advised of the risks and benefits related to participating in **any** paired donation program
- Participants will be informed of potentially adverse events and protected from coerced donation

Proposed Solutions

- Require informed consent for paired candidates and donors, non-directed donors, and bridge donors participating in ANY KPD program
- Intended to supplement existing requirements in *Policy 14.3: Informed Consent Requirements*

Public Comment Themes

- Compliance/Regulatory/Administrative Burden
 - *Committee Response:*
 - Burdens are outweighed by need to inform
- Participant Confusion
 - *Committee Response:*
 - Informed consent is similar to discussing other general risks associated with transplantation
 - Risks may be different in each KPD program and participants should be informed
- Shipping Risks
 - *Committee Response:*
 - Clarified supporting evidence on shipping risks
 - Retained scope to inform of “other potentially negative consequences”

What Members will Need to Do

- Consent patients based upon the new policy.
- No change to the current routine monitoring of OPTN members.
 - Members are required to provide documentation as requested.
- This proposal does not require programming.
- Implementation Date: December 1, 2015

Overall Project Impact

Product

Policy

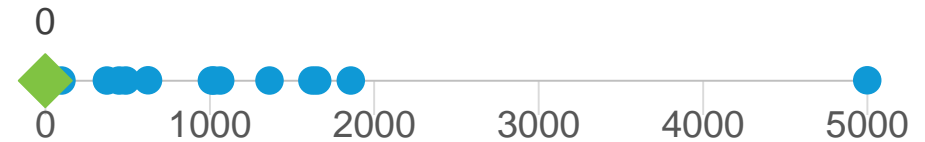
Target Population Impact:

Living Donors

Transplant Candidates and Recipients

Total IT Implementation Hours

0/16,680



Total Overall Implementation Hours

295/23,685



Board Policy Group Recommendation

- Discussion agenda, approve

Amendment 1 to Resolution 22 (page 105)

- Line 38, after 6. The KPD program's remedy for failed exchanges
- Insert
and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
- Line 73, after 9. The KPD program's remedy for failed exchanges
- Insert
and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list

Resolution 22 (page 99)

- RESOLVED, that additions and changes to Policies 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), as set forth below, are hereby approved, effective December 1, 2015.