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
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
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.