



Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation

*Living Donor Committee
December 1-2, 2015*

The Problem

- Members requested clarification re: which policies apply to domino donors
- Members have voiced concerns that some policies are not applicable and constitute undue burden for these patients
- The Committee recognized that there is an additional class of donors who could face similar issues: individuals who have an organ removed as treatment for a medical condition (but who do not receive a transplant)

Proposed Solutions

- Add definitions for domino donor and non-domino therapeutic donor to policy
- Identify policies that protect domino donors, non-domino therapeutic donors and their recipients
- Avoid policy barriers that might prevent a domino donor or non-domino therapeutic donor organ from being transplanted

Strategic Plan Alignment

1: Increase the Number of Transplants

- By establishing minimum requirements for domino donors and non-domino therapeutic donors

4: Promote living donor and transplant recipient safety

- By establishing minimum requirements among domino donors and non-domino therapeutic donors for:
 - informed consent
 - psychosocial
 - medical evaluation
 - follow-up

Post-public comment action

- Changed terminology from “therapeutic donor” to “domino donors and non-domino therapeutic donors”
 - Modified definitions; updated all policy references
- Added two new informed consent requirements:
 - Confidentiality
 - Disclosure of alternative treatment options
- Clarified reporting requirements re: malignancy and infectious diseases
- Adopted plan to monitor numbers of non-domino therapeutic donors

What Members will Need to Do

Recovery hospitals will need to:

- follow new requirements specific to domino donors and non-domino therapeutic donors
- develop and comply with written protocols for domino donors and non-domino therapeutic donor exclusion criteria, considering as appropriate the elements of *Table 14-9: Living Donor Exclusion Criteria*
- Members are expected to comply with the requirements and must provide documentation if requested

Overall Project Impact

Product

Policy modification

Target Population Impact:

Domino Donors and non-Domino Therapeutic Donors
Transplant Candidates and Recipients

Total IT Implementation Hours

200/8,730

Total Overall Implementation and Maintenance Hours

650/15,065

Amendment 1

At a meeting of the OPTN/UNOS Board of Directors convened on December 1-2, 2015, in Richmond, VA, the following amendment is offered.

A resolution to approve changes to policies that establish and clarify requirements for domino donors and non-domino therapeutic donors.

Sponsor Prior to Amendment: Living Donor Committee

In the proposal, after all references to “domino” insert “donors”

Resolution 13 (page 85)

- **RESOLVED**, that Policies 1.2 (Definitions), 6.5.F (Allocation of Domino Donor Hearts), 14.1.A (Living Donor Psychosocial Evaluation Requirements); 14.2.A ILDA Requirements for Living Donor Recovery Hospitals; 14.3 (Informed Consent Requirements); 14.4.B (Living Donor Medical Evaluation Requirements); 14.6.B (Placement of Non-directed Living Donor Kidneys); 14.6.C (Transplant Hospital Acceptance of Living Donor Organs); 14.9 (Requirements for Domino Donors and non-Domino Therapeutic Living Donation; 14.9.A (Informed Consent Requirements for Domino Donors and non-Domino Therapeutic Donors); 14.9.B (Psychosocial and Medical Evaluation Requirements for Domino Donors and non-Domino Therapeutic Donation); and 14.9.C (Recovery of Domino Donors and non-Domino Therapeutic Donor Organs); 14.6.D (Acceptance of Domino Donors and non-Domino Therapeutic Donor Organs); 14.9.E (Reporting and Data Submission Requirements for Domino Donors and non-Domino Therapeutic Donors); 18.1 (Data Submission Requirements) are modified as set forth in Exhibit A, pending implementation and notice to OPTN members.