

Guidance Document for VCAs from Living Donors

*VCA Committee
June 2015*

The Problem

- VCA included under OPTN Final Rule as “covered human organ”
- HHS: definition of VCA doesn’t prohibit living VCA donation and OPTN has oversight over living VCA donation
- Numerous comments received for Fall 2014 VCA implementation proposal objected to inclusion of living VCA donors

Strategic Plan Alignment

Goal 5: Promote living donor safety

- Provide guidance on living VCA donors

Proposed Solutions

- Guidance document to respond to public concern about living VCA donation and clear need for education
- Guidance document addresses:
 - General considerations regarding VCA types that may be suitable to consider from living donors
 - Criteria for living VCA recovery programs
 - Recommendations on the informed consent and medical and psychosocial evaluation of living VCA donors
- Collaboration with other committees
 - Living Donor Committee
 - Ethics Committee

Working Group

Sue McDiarmid, M.D. –
transplant medicine,
Chair VCA Committee

Scott Levin, M.D. –
reconstructive surgery,
Vice-Chair VCA
Committee

Rich Luskin, M.P.A. –
organ procurement,
Vice-Chair VCA
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Gerald Brandacher, M.D.
– reconstructive surgery,
VCA Committee

Bo Pomahac, M.D.–
reconstructive surgery,
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Mary Amanda Dew,
Ph.D. – psychiatry, Chair
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Christie Thomas, M.D. –
transplant medicine,
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Krista Lentine, M.D.,
Ph.D. – transplant
medicine, Living Donor
Committee

Brad Kornfeld, J.D. –
OPTN Board member,
past member of Living
Donor Committee

Randy Schaffer, M.D. –
transplant surgery,
Living Donor Committee

Sanjay Kulkarni, M.D. –
transplant surgery,
Living Donor Committee

Peter Reese, M.D. –
transplant surgery, Chair
Ethics Committee

Elisa Gordon, Ph.D.,
M.P.H. – medical
anthropology, Vice-Chair
Ethics Committee

What Members will Need to Do

- Member transplant centers should reference the guidance document for:
 - Program recommendations
 - Recommendations for informed consent
 - Recommendations for medical and psychosocial evaluations

Overall Project Impact

Product

Guidance Document for VCAs from Living Donors

Target Population Impact:

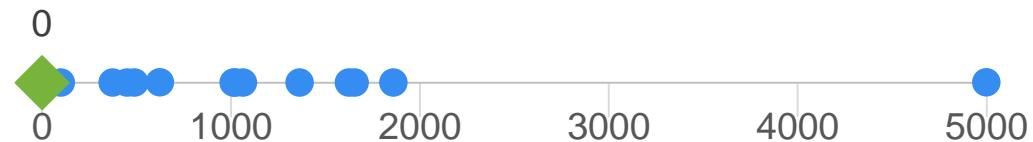
Living Donors

Transplant Hospital and OPO staff

General Public

Total IT Implementation Hours

0/16,680



Total Overall Implementation Hours

30/23,685



Board Policy Group Recommendation

- 0-Approve without further discussion
- 1-Approve but discuss
- 1-Denial but discuss
- 7-No recommendation but discuss

Amendment 1

- Line 219
- Strike
- surrogacy and

Amendment 1

- Lines 232-236
- Strike
- Therefore, when the transplant team evaluates the risk-benefit ratio for the living VCA donor, it is critical to consider that the recipient may have other non-transplant options available. These might include use of autologous tissue, continuing to wait for a deceased VCA donor transplantation, prostheses, or adoption or surrogacy in the case of uterus transplantation.
- Insert
- Therefore, when the transplant team evaluates the risk-benefit ratio for the living VCA donor, it is critical to consider and discuss with the recipient and donor, that the recipient may have other non-transplant options available. These might include use of autologous tissue or continuing to wait for a deceased VCA donor.

Resolution 21 (page 98)

- RESOLVED, that the Guidance Document for VCAs from Living Donors, as set forth in Exhibit D of the VCA Committee's report to the Board, is hereby approved, effective June 2, 2015.