

Modify Living Donor Policy to Include Living VCA Donors

OPTN Living Donor Committee

Purpose of Proposal

- Establish safeguards for living VCA donors
- Create living donor compliance standards for VCA programs

Proposal

- Expands living donation policy to cover all living donors, including VCA
- VCA specific elements added to:
 - Informed Consent Requirements
 - Medical Evaluation Requirements
- This proposal does not change general living donor requirements

Related Proposals

Modify Data Collection on VCA Living Donors

Sponsor: VCA Transplantation Committee

- New data collection for living VCA donors
- Data collection will be managed in UNet

Programming VCA Allocation in UNet

Sponsor: VCA Transplantation Committee

- Updates policy to reflect that VCA from deceased donors will be managed in UNet

Rationale

- Living VCA donation, specifically uterus, rising in U.S.
 - 19 living donor uterus transplants since 2016
- VCA donation is unique, therefore added VCA specific:
 - Informed consent requirements
 - Medical evaluation requirements
- Informed by member expertise, literature, and IRB protocols
- Proposed policy is flexible enough to evolve with the VCA field

Informed Consent Requirements

Living non-genitourinary VCA organ donors

Potential surgical risks:

- Loss of function
- Physical disability
- Physical disfigurement

Living genitourinary VCA organ donors

Potential surgical risks:

- Bowel injury
- Decreased fertility (male)
- Inability to bear children (female)
- Loss of function
- Need for hormonal replacement therapy
- Pain or discomfort with intercourse
- Physical disfigurement (male)
- Urinary tract injury or dysfunction

Informed Consent Requirements

Living non-genitourinary VCA organ donors

Potential psychosocial risk:
Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome

Potential financial impacts:
Procedure may not be covered by health insurance

Living genitourinary VCA organ donors

Potential psychosocial risk:
Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome

Potential financial impacts:
Procedure may not be covered by health insurance

Medical Evaluation Requirements

Type of donor:	Requirements:
All VCA Donors	Transmissible Disease Screening: <ul style="list-style-type: none">• Toxoplasma
Uterus Donors	<ul style="list-style-type: none">• Gynecological and obstetric history including prior childbirth• Pap smear• Pelvic exam• Radiological assessment to determine uterus is suitable for transplant• Transmissible disease screening:<ul style="list-style-type: none">• Bacterial vaginosis• Chlamydia• Gonorrhea• Herpes• HPV• Trichomoniasis• Fungal screening

Member Actions

- VCA programs become familiar with new requirements
 - Similar to requirements for other living donor types with some unique elements for VCA
- Include new requirements into hospital protocols
 - Informed consent requirements
 - Medical evaluation requirements

Feedback Requested

- Are the proposed requirements clear enough?
- Thoughts on specific informed consent and medical evaluation requirements?
- What else should be included?
- Should toxoplasma be a required test for all living donors (not just VCA)?

Please introduce yourself when you speak

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Feedback is summarized and shared as public comment