

Notice of OPTN Policy Changes

Modify Living Donor Policy to Include Living VCA Donors

Sponsoring Committee:	Living Donor
Policies Affected:	<i>14.1.A: Living Donor Psychosocial Evaluation Requirements</i> <i>14.2.A: ILDA Requirements for Living Donor Recovery Hospitals</i> <i>14.3: Informed Consent Requirements</i> <i>14.4.A: Living Donor Medical Evaluation Requirements</i> <i>14.4.D Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs</i>
Public Comment:	August 2020 – October 2020
Board Approved:	June 14, 2021
Effective Date:	September 1, 2021

Purpose of Policy Changes

The policy change would ensure all living donors, including VCA donors, are covered by OPTN living donor policy. VCAs are organs covered by the OPTN, therefore policies have been developed to establish safeguards for living VCA donors and create living donor compliance standards for VCA programs.

Proposal History

In 2014 the OPTN Board of Directors made VCA an organ type under the purview of the OPTN. Concurrently, living donation policy was developed to cover living liver, kidney, lung, pancreas, and intestine donors specifically. The first living donor VCA transplant was a uterus transplant performed in 2016. Uterus transplants have since increased in frequency and most have been made possible through living donation. Living donation of other VCA types may be performed in the U.S. in the future. The Living Donor Committee developed a proposal to ensure living donors of covered VCAs are covered by the same policy protections as all other living donors. The proposal was released for public comment in August 2020 and was broadly supported. The Committee made minimal post-public comment changes to the originally proposed policy language but did remove gender-specific language from surgical risks for covered genitourinary VCA organs. Additionally, the policy language has been updated to incorporate the VCA clarification definition found in the *Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts* policy notice.

Summary of Changes

- Updates Living Donor policy to cover all living donors
- Adds Informed Consent policy specific to living donors of covered VCAs

- Distinguishes between non-genitourinary and genitourinary VCA living donors
- Identifies potential surgical, psychosocial, and financial risks unique to VCA donation
- Adds Medical Evaluation Requirements policy specific to living donors of covered VCAs
 - Includes toxoplasma as a required test for all living donors of covered VCAs
 - Also includes requirements for collection of medical history, anatomic assessment, and specific testing for living uterus donors

Implementation

VCA-specific transplant programs will need to become familiar with and comply with OPTN policy for living donors of covered VCAs.

The OPTN will notify and educate the community of the changes and will incorporate the new policy into monitoring and post-implementation review plans.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

14.1 Psychosocial Evaluation Requirements for Living Donors

14.1.A Living Donor Psychosocial Evaluation Requirements

~~Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung, and intestine donors.~~

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, masters prepared social worker, or licensed clinical social worker prior to organ recovery. Documentation of the psychosocial evaluation must be maintained in the living donor medical record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome.
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*.
3. A review of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder.
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision.
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation.
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor

- has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended.
8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support.
 9. The determination that the living donor understands the potential financial implications of living donation.

14.2 Independent Living Donor Advocate (ILDA) Requirements

14.2.A ILDA Requirements for Living Donor Recovery Hospitals

~~Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine, and lung donors.~~

For any living donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an ILDA team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor. All ILDA requirements must be completed prior to organ recovery.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate.
4. Review and document whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
 - a. Informed consent process as described in *Policy 14.3: Informed Consent Requirements*
 - b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
 - c. Surgical procedure
 - d. Follow-up requirements, and the benefit and need for participating in recovery hospital's requirements according to *Policies 18.1: Data Submission Requirements, 18.5: Living Donor Data Submission Requirements, and 18.6: Reporting of Living Donor Adverse Events*

14.3 Informed Consent Requirements

The living donor recovery hospital is responsible for obtaining and documenting informed consent prior to organ recovery. Informed consent requirements ~~apply to living kidney, liver, pancreas, intestine, and lung donors~~ and must include *all* of the components in *Tables 14-1 through 14-5*. Documentation of informed consent must be maintained in the living donor medical record.

Table 14-4: Additional Requirements for the Informed Consent of Living Donors of Covered VCAs

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:
<p><u>Disclose to all living donors of covered VCAs other than covered genitourinary organ VCAs</u></p>	<p><u>There are surgical, psychosocial, and financial risks associated with living donation of covered non-genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, all of the following:</u></p> <ul style="list-style-type: none"> • <u>Potential surgical risks:</u> <ul style="list-style-type: none"> • <u>Loss of function</u> • <u>Physical disability</u> • <u>Physical disfigurement</u> • <u>Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome</u> • <u>Potential financial impacts: Procedure may not be covered by health insurance</u>
<p><u>Disclose to all living donors of covered genitourinary organ VCAs</u></p>	<p><u>There are surgical, psychosocial, and financial risks associated with living donation of covered genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, all of the following:</u></p> <ul style="list-style-type: none"> • <u>Potential surgical risks:</u> <ul style="list-style-type: none"> • <u>Bowel injury</u> • <u>Need for hormonal replacement therapy</u> • <u>Pain or discomfort with intercourse</u> • <u>Partial or complete loss of organ-specific function including reproductive function</u> • <u>Physical disfigurement</u> • <u>Urinary tract injury or dysfunction</u> • <u>Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome</u> • <u>Potential financial impacts: Procedure may not be covered by health insurance</u>

As part of the informed consent process, recovery hospitals must also provide transplant recipient outcome and transplanted organ survival data to living donors according to *Table 14-45*. The requirements in *Table 14-5* do not apply to donors of covered VCAs.

Table 14-45: Required Recipient Outcome and Transplanted Organ Survival Data

If the recovery hospital and the recipient hospital:	Then the recovery hospital must provide the living donor with:	Including <i>all</i> the following information:
Are the same	Both national and that hospital’s program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The hospital’s 1-year patient and transplanted organ survival • Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	Both national and the recipient hospital’s program-specific transplant recipient outcomes from the most recent SRTR program-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The recipient hospital’s 1-year patient and transplanted organ survival • Notification about all CMS outcome requirements not being met by the recipient hospital
Will not be the same and the recipient hospital is not known	National transplant recipient outcomes from the most recent SRTR reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival

14.4 Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

~~Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or intestine donors.~~

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-56* through *14-810* below.

14.4.D Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

Table 14-9: Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

<u>This evaluation must be completed:</u>	<u>For living donors of these organs:</u>	<u>Including evaluation for and assessment of this information:</u>
<u>Transmissible disease screening</u>	All covered VCAs	Infectious disease testing must be performed in a <u>CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include all of the following:</u> <ul style="list-style-type: none"> • <u>Toxoplasma Immunoglobulin G (IgG) antibody test</u>
<u>Additional specific medical history</u>	<u>Uterus</u>	<ul style="list-style-type: none"> • <u>Gynecological and obstetric history including prior childbirth</u>
<u>Additional specific tests</u>	<u>Uterus</u>	<ul style="list-style-type: none"> • <u>Pap smear</u>
<u>Additional anatomic assessment</u>	<u>Uterus</u>	<ul style="list-style-type: none"> • <u>Pelvic exam</u> • <u>A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation</u>
<u>Additional transmissible disease screening</u>	<u>Uterus</u>	Infectious disease testing must be performed in a <u>CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include all of the following:</u> <ul style="list-style-type: none"> • <u>Bacterial Vaginosis (Gardnerella Vaginalis)</u> • <u>Chlamydia by nucleic acid test (NAT)</u> • <u>Gonorrhea by nucleic acid test (NAT)</u> • <u>Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test</u> • <u>Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA</u> • <u>Trichomoniasis</u> • <u>Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)</u>