

Briefing to the OPTN Board of Directors on

Modify Living Donor Policy to Include Living VCA Donors

OPTN Living Donor Committee

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Modify Living Donor Policy to Include Living VCA Donors

<i>Affected Policies:</i>	<p>14.1.A: <i>Living Donor Psychosocial Evaluation Requirements</i></p> <p>14.2.A: <i>ILDA Requirements for Living Donor Recovery Hospitals</i></p> <p>14.3: <i>Informed Consent Requirements</i></p> <p>14.4.A: <i>Living Donor Medical Evaluation Requirements</i></p>
<i>Sponsoring Committee:</i>	<i>Living Donor</i>
<i>Public Comment Period:</i>	<i>August 4, 2020 – October 1, 2020</i>
<i>Board of Directors Date:</i>	<i>June 14, 2021</i>

Executive Summary

The Living Donor Committee (the Committee) is proposing to update *OPTN Policy 14: Living Donation* to include all living donors and add specific elements for living vascularized composite allograft (VCA) donors. Living VCA donation, particularly uterus donation, has been steadily rising in the U.S. since 2016. However, current OPTN living donor policy does not include living VCA donation. The purpose of this proposal is to establish safeguards for living VCA donors and compliance standards for living VCA donor programs. This proposal would update living donor policy to apply to all living donors, as well as add specific elements for covered VCAs to informed consent and medical evaluation requirements. The Committee identified there are unique considerations for living VCA donors and are proposing adding VCA-specific psychosocial, surgical, and financial risks to informed consent requirements. Also, the Committee is proposing the addition of medical evaluation requirements to include transmissible disease screening and other tests specific to covered VCAs, primarily uterus.

To inform these recommendations, the Committee established the Living Donor VCA Workgroup (the Workgroup), comprised of members from the Living Donor, VCA, and Ethics Committees as well as a living uterine donor. The Committee also collaborated with the Disease Transmission Advisory Committee on the medical evaluation requirements. This proposal was developed in conjunction with the VCA Committee's related proposals, *Modify Data Collection on VCA Living Donors* and *Programming VCA Allocation in UNet*, which were also released for public comment in August 2020 and approved by the Board in December 2020.^{1,2}

¹ *Briefing to the OPTN Board of Directors on Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf (accessed April 2, 2021).

² *Briefing to the OPTN Board of Directors on Programming VCA Allocation in UNet*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4211/bp_202012_programming-vca-allocation-in-unet.pdf (accessed April 2, 2021).

Background

OPTN Policy 14: Living Donation is a list of requirements for transplant hospitals involved in living organ donor transplants. The policy includes minimum requirements for the psychosocial evaluation, informed consent, and medical evaluation of living donors. Living vascularized composite allograft (VCA) donors are not currently included in living donor policy.

Original policy references to living donation were housed in kidney and liver specific policies and were limited to the psychosocial and medical evaluation of those donors. In 2013, a subcommittee of the Living Donor Committee (the Committee) determined that there should be minimum, common standards and protections for all living donors and a living donor specific policy section should be developed.³

From 2013 to 2015, the Committee worked on consolidating living donor policies into the current format and originally intended to cover all living donors. Concurrently, the OPTN Final Rule was amended by the Secretary of the U.S. Department of Health and Human Services (HHS) to include VCAs as “covered human organs” effective July 3, 2014.⁴ With that change, the OPTN was charged with the oversight of VCA procurement and transplantation. In 2014 the OPTN Board of Directors made VCA an organ type under the purview of the OPTN.⁵

With the incorporation of VCA as an organ type under the purview of the OPTN, the Committee considered if it was feasible to include VCA in living donor policy. Given the unique nature of VCA transplant and community concern, the Committee was not confident the requirements included in living donor policies were robust enough to cover the possibility of living VCA donation.⁶ The Committee was cautious of the risks associated with including all living donors as this meant there may be insufficient guardrails or procedures for living VCA donors. In response, the Committee decided to revise living donor policies to specifically name organs covered by the policy by type: liver, kidney, lung, pancreas, and intestine.⁷ It was felt at the time that the majority of VCA donations would come from deceased donors and living donation would rarely be practiced as living uterine donation was a brand new concept. Living donor policy to this day only applies to the organs listed in the policy.⁸

In 2015, the Living Donor, VCA, and Ethics Committees formed a workgroup to develop the guidance document, *VCAs from Living Donors*.⁹ Concerns had been raised by committee members regarding the lack of definitions of VCA organs for which living donation may and may not be suitable, the absence of program requirements for safe live VCA donor recovery, and the lack of policies for the informed

³ *Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation for Living Donor*, OPTN Living Donor Committee, November 2014, https://optn.transplant.hrsa.gov/media/1451/pubcommentprosub_337.pdf (accessed April 2, 2021).

⁴ Department of Health and Human Services, Final rule, “Organ Procurement and Transplantation Network, 42 CFR Part 121,” *Federal Register* 78, No. 128 (July 3, 2013). <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf> (accessed April 2, 2021).

⁵ Policy Notice, Changes to OPTN Bylaws and Policies from actions at June Board of Directors Meeting, July 1, 2014, https://optn.transplant.hrsa.gov/media/1279/policynotice_20140701.pdf (accessed April 2, 2021).

⁶ *VCAs from living donors*, OPTN VCA Committee, June 2015, <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/> (accessed April 2, 2021).

⁷ *Ibid.*

⁸ OPTN Policy 14, *Living Donation*, (April 26, 2021).

⁹ *Ibid.*

consent, medical, and psychosocial evaluation of living VCA donors. The drafting of this document was a response to these concerns, however the guidance is non-binding. The fundamental tenet of the document is that guidance and future policy must be specific to VCA categories.

“It should be recognized that there are many different types of VCA donation and given the individualized nature of the reconstructive and non-reconstructive VCA procedures, the specific risks of each cannot be encapsulated or covered by general principles.”¹⁰

The field of VCA transplantation was introduced in 1998 following the first hand transplant in France.¹¹ This case introduced the concept of “restorative” VCA transplants, which are now accepted as a viable option for patients with reconstructive needs that would be more difficult with traditional methods. Restorative VCA transplantation is intended to “restore musculoskeletal function and/or body form to the affected recipient in the setting of trauma, tumor, infection, and congenital differences”.¹²

Non-restorative VCA, such as uterine transplantation, repairs lost or missing non-essential function (i.e. reproductive) to an otherwise healthy individual. The first documented uterus transplant from a deceased donor was reported in 2002 in Saudi Arabia.¹³ In 2016, the first U.S. uterus transplant was performed at the Cleveland Clinic.¹⁴ Between September 2016 and March 2021 there have been 31 uterine transplants, 19 of which have been from living donors (**Figure 1**). These transplants occurred under program-specific Institutional Review Board (IRB) clinical trials with pre-determined protocols and procedures. It is assumed the 2020 uterine transplant totals have most likely been affected by the COVID-19 pandemic.

¹⁰ VCAs from living donors, OPTN VCA Committee, June 2015, <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/> (accessed April 2, 2021).

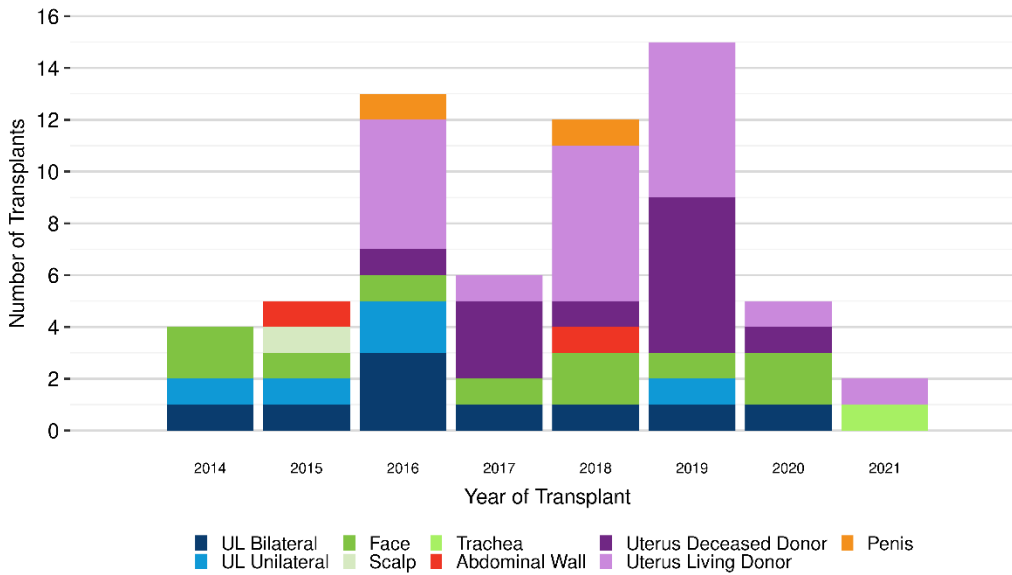
¹¹ Dubernard JM, et al. “Functional results of the first human double-hand transplantation,” *Annals of Surgery*, 2003; 238:128–136. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1422660/> (accessed April 2, 2021).

¹² Ibid.

¹³ Johannesson, Liza and Jarvholm, Stina, “Uterus transplantation: current progress and future prospects,” *International Journal of Women’s Health*, 2016; 8: 43-51. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4751897/> (accessed April 2, 2021).

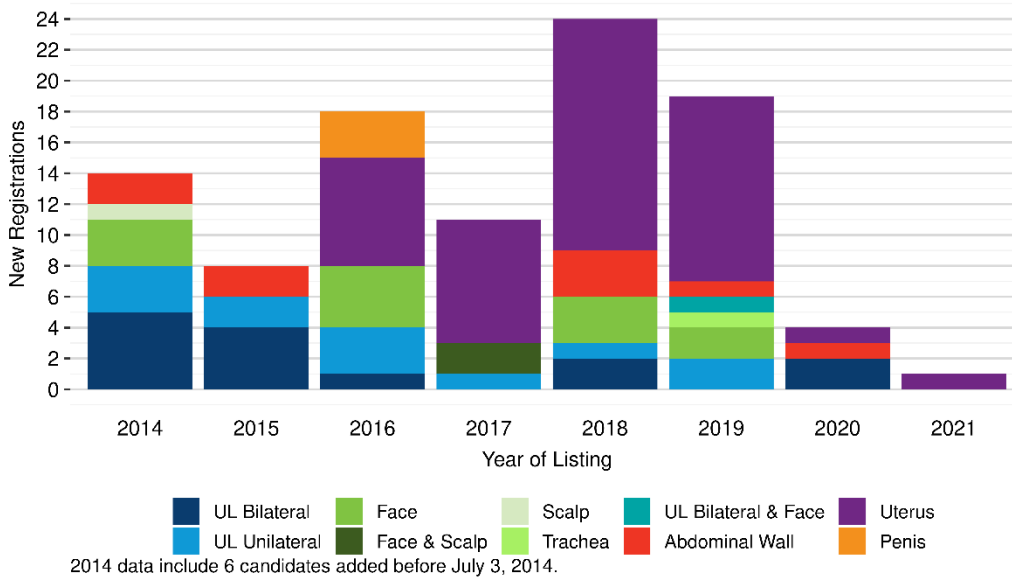
¹⁴ “Cleveland Clinic Performs First Uterine Transplant in U.S.,” *Cleveland Clinic*, February 26, 2016. <https://consultqd.clevelandclinic.org/cleveland-clinic-performs-first-uterine-transplantation/> (accessed April 2, 2021).

Figure 1: VCA Transplants in the U.S.: July 3, 2014 – March 31, 2021¹⁵



Over half of the candidates added to the VCA waiting list since 2016 were uterus candidates, making uterus the most sought-after VCA transplant (**Figure 2**). While other forms of living VCA donation have not been performed in the United States in recent years, the Committee is conscious of the possibility of other forms of living VCA donation developing in the future. For example, a living testicle donation was performed in Serbia in 2019.¹⁶

Figure 2: Additions to the VCA Waitlist in the U.S.: July 3, 2014 – March 31, 2021¹⁷



¹⁵ Based on OPTN data as of March 31, 2021.

¹⁶ Grady, Denise. "Surgeons Transplant a Testicle from One Brother to His Twin," *New York Times*, December 6, 2019. <https://www.nytimes.com/2019/12/06/health/testicles-transplant.html> (accessed April 2, 2021).

¹⁷ Based on OPTN data as of March 31, 2021.

To develop this proposal, the Committee established the Living Donor VCA Workgroup (the Workgroup), comprised of members from the Living Donor, VCA, and Ethics Committees as well as a living uterine donor. The Workgroup members included coordinators, physicians, and surgeons, some of whom represent current uterus transplant programs. The Workgroup also collaborated with the OPTN Disease Transmission Advisory Committee (DTAC) to develop proposed elements for transmissible disease testing under *Policy 14.4: Medical Evaluation Requirements for Living Donors*. The proposal was informed by Committee and Workgroup member expertise, Institutional Review Board (IRB) protocols of existing uterus transplant programs, as well as relevant clinical literature.

Concurrently, the VCA Committee established the VCA Living Donor Data Collection Workgroup to develop a proposal to update the Living Donor Registration (LDR) form, Living Donor Follow-Up (LDF) form, and *Policy 18: Data Submission Requirements* to include VCA living donors in OPTN data collection.¹⁸ Some members served on both workgroups simultaneously and these proposals were designed to complement each other.

Following a review for Final Rule compliance in December 2020, the OPTN recognized a need to modify the definition of VCAs, including clarifications to the list of body parts covered in VCA-specific policies. This proposal was held from consideration while clarifications to the definition of VCA and related policies and bylaws were crafted. A technical correction has been submitted for the Board’s consideration; this proposal includes language reflecting the approach of the technical correction.¹⁹

Purpose

Living VCA donors are not currently covered by *Policy 14: Living Donation*. The proposed policy change would ensure all living donors, including VCA donors, are covered by OPTN living donor policy. **Table 1** details the updated list of covered VCA body parts (covered VCAs) to be implemented in OPTN policy in 2021:²⁰

Table 1: Covered Vascularized Composite Allograft body parts (covered VCAs)

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall

¹⁸ *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/> (accessed October 27, 2020).

¹⁹ *Mini-Brief to the OPTN Board of Directors: Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts*, OPTN VCA Committee, June 2021.

²⁰ *Ibid.*

Covered VCA(s)	Type:
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

In 2006, the Secretary of HHS directed the OPTN “to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule”.²¹ As VCAs are organs, the OPTN has the authority and responsibility to develop policies regarding living donors of covered VCAs and recipients of covered living VCA donor organs pursuant to the 2006 directive. Additionally, two of the OPTN’s strategic goals are to “improve waitlisted patient, living donor, and transplant recipient outcomes,” and “to promote living donor and transplant recipient safety.”²² Given the rapid increase of living uterus donation and transplant, the Living Donor and VCA Committees identified a need to modify current policy and data collection practices for living donors of covered VCAs. Various literature has also stressed the importance for the OPTN to develop formal policies and data submission requirements on live uterus donation.^{23, 24, 25}

Public Comment Sentiment

This proposal was issued for public comment from August 4, 2020, to October 1, 2020. The feedback is described below. In addition to feedback on the proposal, the Committee requested feedback on whether the proposed language was sufficiently clear enough to be incorporated into hospital protocol; whether the potential surgical, psychosocial, and financial risks for genitourinary and non-genitourinary donors are agreeable; whether the medical evaluation requirements for VCA are agreeable; if there are

²¹ Department of Health and Human Services, Health Resources and Services Administration, “Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines,” 71 Fed. Reg. 34946, 34948 (June 16, 2006). <https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-and-transplantation-network-optn-living-donor> (accessed April 2, 2021).

²² OPTN Strategic Plan, 2018-2021,

https://optn.transplant.hrsa.gov/media/2392/executive_publiccomment_strategicplan_20180122.pdf (accessed April 2, 2021).

²³ VCAs from living donors, OPTN VCA Committee, June 2015, <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/> (accessed April 2, 2021).

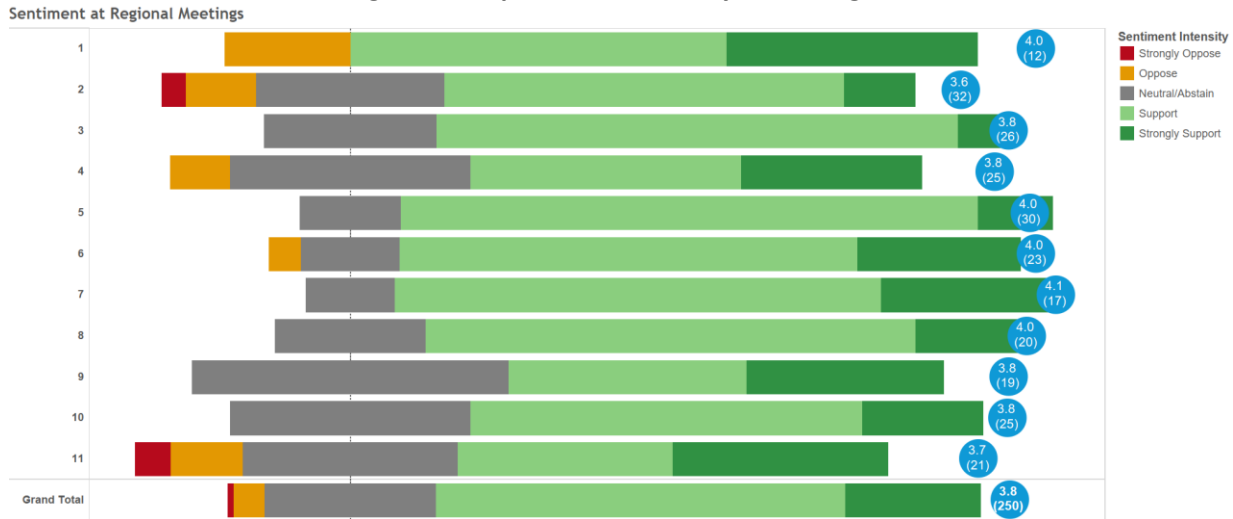
²⁴ Allyse, Megan, et al. “American Society for Reproductive medicine position statement on uterus transplantation: a committee opinion,” *Fertil Steril*, 2018; 110: 605-610. <https://pubmed.ncbi.nlm.nih.gov/30196945/> (accessed April 2, 2021).

²⁵ Horvat, Margaret and Iltis, Ana, “What Are Good Guidelines for Evaluating Uterus Transplantation?,” *AMA Journal of Ethics*, 2019; 21: 988-995. <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2019-10/msoc2-1911.pdf> (accessed April 2, 2021).

other VCA or uterine-specific requirements that should be incorporated; and if toxoplasma should be a required test for all living donors.

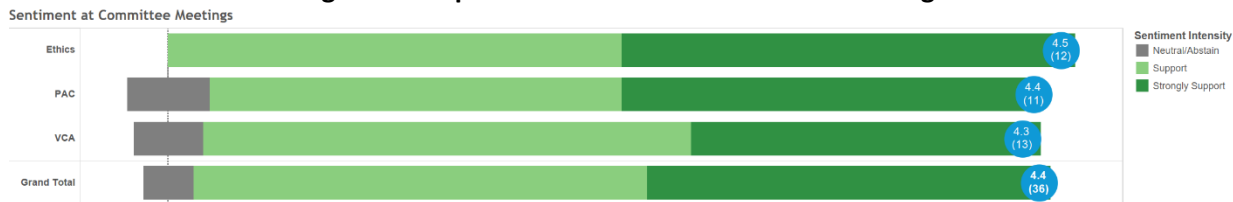
Public comment sentiment indicated support for this proposal across all 11 OPTN regions, as shown in **Figure 3**.

Figure 3: Proposal Sentiment by OPTN Region²⁶



The Patient Affairs Committee, the Ethics Committee, the VCA Committee, and the Disease Transmission Advisory Committee were asked to review the proposal and provide feedback. All four committees supported the proposal, though only three indicated numerical sentiment as shown in **Figure 4**. Additionally, the Patient Affairs Committee offered feedback that compelled the Committee to make a post-Public Comment change, as described in the Proposal section below.

Figure 4: Proposal Sentiment at Committee Meetings²⁷



The proposal was supported by the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the Association of Organ Procurement Organizations (AOPO), and the Society for Transplant Social Workers (STSW).

²⁶ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

²⁷ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committees only includes attendees at that committee meeting. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Proposal for Board Consideration

The proposal revises living donor policies to make them applicable to all living donors. Additionally, the proposal would add elements specific to living donation of covered VCAs to informed consent and medical evaluation requirements. The proposed changes, along with the VCA Committee's *Modify Data Collection on VCA Living Donors* proposal, would ensure living donor safety, monitor member compliance, and establish an avenue for assessing outcomes for living donors of covered VCAs.²⁸

Updating Policy to Cover All Living Donors

Current policy includes language under *Policies 14.1, 14.2, 14.3, and 14.4* that specify the policies apply to living kidney, liver, pancreas, lung, and intestine donors. The proposed update removes this language entirely and in effect would cause the policy to apply to all living donors that donate organs covered by the OPTN. "Living donor" is defined in OPTN policy as "a living individual from whom at least one organ is recovered for transplantation".²⁹ Furthermore, the definition of "organ" is defined in the Final Rule as:

*"Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled 'For use in organ transplantation only.'"*³⁰

This aspect of the proposal was broadly supported throughout public comment and no post-public comment changes were made.

Informed Consent

Current policy includes general informed consent requirements under *Table 14-1: Requirements for Living Donor Informed Consent* for all covered living donors.³¹ There are also additional tables with requirements unique to living kidney and liver donors. Similarly, the Committee proposes adding a new table to informed consent policy specific to living donors of covered VCAs. The proposed elements are summarized in **Table 2**.

²⁸ *Briefing to the OPTN Board of Directors on Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf (accessed April 2, 2021).

²⁹ OPTN Policy 1.2, *Definitions* (April 26, 2021).

³⁰ OPTN Final Rule, 42 CFR § 121.2 (July 20, 2020). The definition of "Organ" in OPTN Policy 1.2: Definitions, mirrors the definition in the Final Rule.

³¹ OPTN Policy 14.3, *Informed Consent Requirements* (April 26, 2021).

Table 2: 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>Disclose to all living donors of covered VCAs other than covered genitourinary organ VCAs</p>	<p>There are surgical, psychosocial, and financial risks associated with living donation of covered non-genitourinary organ VCAs, which may be temporary or permanent and include, but are not limited to, <i>all</i> of the following:</p> <ul style="list-style-type: none"> • Potential surgical risks: <ul style="list-style-type: none"> • Loss of function • Physical disability • Physical disfigurement • 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
<p>Disclose to all living donors of covered genitourinary organ VCAs</p>	<p>There are surgical, psychosocial, and financial risks associated with living donation of covered genitourinary organ VCAs, which may be temporary or permanent and include, but are not limited to, <i>all</i> of the following:</p> <ul style="list-style-type: none"> • Potential surgical risks: <ul style="list-style-type: none"> • Bowel injury • Need for hormonal replacement therapy • Pain or discomfort with intercourse • Partial or complete loss of organ-specific function including reproductive function • Physical disfigurement • Urinary tract injury or dysfunction • 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

The table divides living donors of covered VCAs into two categories: non-genitourinary and genitourinary. In early drafting, the table distinguished between living non-reproductive and reproductive VCA donors. The language was changed to “covered VCAs other than covered genitourinary organ VCAs” and “covered genitourinary organ VCAs” to align with language in the new definition of covered VCAs (**Table 1**).^{32,33} Tying this language to the definition of covered VCAs in *OPTN Policy 1* would also ensure the policy is aligned with the definition of covered VCAs if it were to be

³² *Mini-Brief to the OPTN Board of Directors: Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts*, OPTN VCA Committee, June 2021.

³³ Meeting Summary for May 6, 2020 meeting, OPTN Living Donor VCA Workgroup, <https://optn.transplant.hrsa.gov/media/3791/20200506-living-donor-vca-workgroup-meeting-summary.pdf> (accessed April 2, 2021).

updated further in the future. The two categories have similar informed consent requirements but the differences are unique enough to warrant the distinction between the two.

The proposed table was drafted with the goal of providing language broad enough to encompass where the VCA field may evolve and ensure patient safety and compliance standards. The Committee emphasized the proposed table is not an attempt to influence the direction of the field of VCA, but rather establishes policy to protect and inform living donors in connection with two distinct types of VCA transplant (covered non-genitourinary organ and covered genitourinary organ). The Committee also recognizes the need to periodically revisit the VCA policy as the field evolves.

Potential Surgical Risks

The largest differences between the covered non-genitourinary organ and covered genitourinary organ categories fall under the potential surgical risks. The potential to be able to donate other types of VCA organs as the field evolves warranted the addition of three surgical risks for non-genitourinary organs that are not covered in the general informed consent requirements. These three potential surgical risks are:

- Loss of function
- Physical disability
- Physical disfigurement

General requirements already require programs to disclose the potential for scarring. However, the Committee felt the wide range of possible VCA donations had the potential to cause physical disfigurement, disability, and loss of function for the donor beyond general scarring (ex. limb, abdominal wall). Loss of function and physical disfigurement are found in the covered genitourinary organ category as well.

For the covered genitourinary organ category, the Workgroup originally listed potential surgical risks for uterus donors only, with “inability to bear children” as an absolute risk. However, through Workgroup and Committee discussions, the decision was made to include potential surgical risks that would cover other potential genitourinary organ donation (ex. testicular transplant).^{34, 35}

The proposed table released for public comment included “decreased fertility (male)”, “inability to bear children (female)”, “loss of function”, and “physical disfigurement (male)” as potential surgical risks for genitourinary organ donation. After Public Comment, the Committee removed the gender-specific language for surgical risks to be consistent with the spirit of keeping the requirements broad enough to be applicable to various types of genitourinary donation. The Committee recognized those surgical risks that were gender-assigned may need to be reworded to be broadly applicable. Therefore, “decreased fertility”, “inability to bear children”, and “loss of function” were consolidated into “Partial or complete loss of organ-specific function including reproductive function”.

³⁴ Meeting Summary for May 6, 2020 meeting, OPTN Living Donor VCA Workgroup, <https://optn.transplant.hrsa.gov/media/3791/20200506-living-donor-vca-workgroup-meeting-summary.pdf> (accessed April 2, 2021).

³⁵ Grady, Denise. “Surgeons Transplant a Testicle from One Brother to His Twin,” *New York Times*, December 6, 2019. <https://www.nytimes.com/2019/12/06/health/testicles-transplant.html> (accessed April 2, 2021).

Recognizing some of the potential surgical risks would not be broadly applicable (ex. inability to bear children), the Committee amended the potential surgical risks for genitourinary organ donation to include:

- Bowel injury
- Need for hormonal replacement therapy
- Pain or discomfort with intercourse
- Partial or complete loss of organ-specific function including reproductive function
- Physical disfigurement
- Urinary tract injury or dysfunction

General requirements currently require programs to disclose “bowel obstruction” as a potential surgical risk. However, “bowel injury” was added as a potential surgical risk here due to the proximity of genitourinary organs (such as uterus) to the rectum.³⁶ These risks were informed by the clinical expertise of Workgroup members, existing literature, as well as IRB protocols of existing uterus transplant programs.^{37, 38, 39, 40, 41, 42, 43, 44, 45}

The American Society of Transplantation (AST) submitted a public comment recommending more language be added to the potential surgical risk of urinary tract injury or dysfunction to specify the potential for short term and long term consequences. Upon review of the table as proposed, the Committee felt the language “may be temporary or permanent” was sufficient.

Psychosocial Risks

Current informed consent policy requires programs to disclose psychosocial risks to the donor, including “feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies”.⁴⁶ The Workgroup discussed editing this requirement, as VCA transplant does not necessarily occur due to disease. For example, uterus transplants specifically occur so the recipient may experience pregnancy and give birth. A uterus transplant is considered

³⁶ Meeting Summary for April 22, 2020 meeting, OPTN Living Donor VCA Workgroup, <https://optn.transplant.hrsa.gov/media/3790/20200422-living-donor-vca-workgroup-meeting-summary.pdf> (accessed April 2, 2021).

³⁷ Baylor Research Institute, *Uterine Transplantation and Pregnancy Induction in Women affected by Absolute Uterine Factor Infertility (Donor)*, Institutional Review Board Protocols, 2019.

³⁸ Brigham and Women’s Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

³⁹ Allyse, Megan, et al. “American Society for Reproductive medicine position statement on uterus transplantation: a committee opinion,” *Fertil Steril*, 2018; 110: 605-610. <https://pubmed.ncbi.nlm.nih.gov/30196945/> (accessed April 2, 2021).

⁴⁰ Brännström, Mats, et al. “Uterus Transplant: A Rapidly Expanding Field,” *Transplantation*, 2018; 102: 569-577. <https://pubmed.ncbi.nlm.nih.gov/29210893/> (accessed April 2, 2021).

⁴¹ Johannesson, Liza and Jarvholm, Stina, “Uterus transplantation: current progress and future prospects,” *International Journal of Women’s Health*, 2016; 8: 43-51. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4751897/> (accessed April 2, 2021).

⁴² Horvat, Margaret and Iltis, Ana, “What Are Good Guidelines for Evaluating Uterus Transplantation?,” *AMA Journal of Ethics*, 2019; 21: 988-995. <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2019-10/msoc2-1911.pdf> (accessed April 2, 2021).

⁴³ Kisu, Iori, et al. “Risks for Donors in Uterus Transplantation,” *Reproductive Sciences*, 2013; 20: 1406-1415. <https://journals.sagepub.com/doi/10.1177/1933719113493517> (accessed April 2, 2021).

⁴⁴ O’Donovan, Laura, “Pushing the boundaries: Uterine transplantation and the limits of reproductive autonomy,” *Bioethics*, 2018; 32: 489-498. <https://doi.org/10.1111/bioe.12531> (accessed April 2, 2021).

⁴⁵ Zaami, S, et al. “Advancements in uterus transplantation,” *European Review for Medical and Pharmacological Sciences*, 2019; 23: 892-902. <https://pubmed.ncbi.nlm.nih.gov/30720198/> (accessed April 2, 2021).

⁴⁶ OPTN Policy 14.3, *Informed Consent Requirements* (April 26, 2021).

successful not only by the organ’s function, but by the delivery of a healthy child.⁴⁷ A donation of this nature could have unique psychological meaning for the donor.^{48, 49, 50} Therefore, the Workgroup created language that would address the donor’s potential feelings if the donation did not result in a successful outcome (ex. uterus donation resulting in a successful pregnancy). It was recognized a change to the general informed consent language would affect all living donor programs and could potentially cause significant administrative burden. The Workgroup and the Committee ultimately decided not to change the language in the general informed consent requirement but instead add a potential psychosocial risk unique to covered non-genitourinary organ and covered genitourinary organ VCAs as follows:^{51,52}

- Covered Non-Genitourinary Organ: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome
- Covered Genitourinary Organ: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome

The Patient Affairs Committee recommended adding an additional potential psychosocial risk of “loss of identity” or “loss of gender identity”. The Committee considered the recommendation and recognizes this is a discussion point that is becoming more prominent in the medical community and medical literature. However, the Committee concluded more consultation with subject matter experts would be needed before adding such language to OPTN policy.

Financial Risks

General informed consent policy requires programs to inform living donors of financial risks associated with the possibility of the procedure having a negative impact on their ability to “obtain, maintain, or afford health insurance, disability insurance, and life insurance”.⁵³ The Workgroup felt since VCA transplant is still considered experimental and a donor’s health insurance may not cover their care related to the transplant at all, there was a need to add more robust language related to healthcare within the table for VCA donors.⁵⁴ The proposed table includes language to highlight this additional risk for living donors of covered VCAs.⁵⁵

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

⁴⁷ Ibid.

⁴⁸ Johannesson, Liza and Jarvholm, Stina, “Uterus transplantation: current progress and future prospects,” *International Journal of Women’s Health*, 2016; 8: 43-51. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4751897/> (accessed April 2, 2021).

⁴⁹ Kisu, Iori, et al. “Risks for Donors in Uterus Transplantation,” *Reproductive Sciences*, 2013; 20: 1406-1415. <https://journals.sagepub.com/doi/10.1177/1933719113493517> (accessed April 2, 2021).

⁵⁰ O’Donovan, Laura, “Pushing the boundaries: Uterine transplantation and the limits of reproductive autonomy,” *Bioethics*, 2018; 32: 489-498. <https://doi.org/10.1111/bioe.12531> (accessed April 2, 2021).

⁵¹ Meeting Summary for April 20, 2020 meeting, OPTN Living Donor Committee, <https://optn.transplant.hrsa.gov/media/3792/20200420-living-donor-meeting-summary.pdf> (accessed April 2, 2021).

⁵² Meeting Summary for April 22, 2020 meeting, OPTN Living Donor VCA Workgroup, <https://optn.transplant.hrsa.gov/media/3790/20200422-living-donor-vca-workgroup-meeting-summary.pdf> (accessed April 2, 2021).

⁵³ OPTN Policy 14.3, *Informed Consent Requirements* (April 26, 2021).

⁵⁴ Ibid.

⁵⁵ Brigham and Women’s Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

The AST also submitted a public comment recommending more language be added to the potential financial impact related to degrees of financial risk. Upon review of the table as proposed, the Committee felt the language “may be temporary or permanent” was sufficient.

Medical Evaluation Requirements

Current policy includes medical evaluation requirements under *Table 14-5: Requirements for Living Donor Medical Evaluations* for all covered living donors.⁵⁶ There are also requirements unique to living kidney and liver donors. Similarly, the Committee proposes adding a new table to the medical evaluation requirements policy specific to living donors of covered VCAs. Most of the proposed elements are specific to living uterus donors, but there is one required test that would apply to all living donors of covered VCAs. The proposed elements are summarized in **Table 3**.

Table 3: Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
Transmissible disease screening	All covered VCAs	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> of the following: <ul style="list-style-type: none"> • Toxoplasma Immunoglobulin G (IgG) antibody test
Additional specific medical history	Uterus	<ul style="list-style-type: none"> • Gynecological and obstetric history including prior childbirth
Additional specific tests	Uterus	<ul style="list-style-type: none"> • Pap smear
Additional anatomic assessment	Uterus	<ul style="list-style-type: none"> • Pelvic exam • A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation

⁵⁶ OPTN Policy 14.4, *Medical Evaluation Requirements for Living Donors* (April 26, 2021).

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
Additional transmissible disease screening	Uterus	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> of the following: <ul style="list-style-type: none"> • Bacterial Vaginosis (Gardnerella Vaginalis) • Chlamydia by nucleic acid test (NAT) • Gonorrhea by nucleic acid test (NAT) • Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test • Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA • Trichomoniasis • Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)

Transmissible Disease Screening for all VCA donors

Currently, toxoplasma is a required test for all deceased donors but is not a required test for living donors. The OPTN Disease Transmission Advisory Committee (DTAC) recommended adding this test as a requirement for living donors of covered VCAs as it is especially important for skeletal muscle and uterine type transplants. Testing for toxoplasma is important for uterine transplant due to the potential for reactivation under immunosuppression and to infect a fetus, as fetal infection (congenital toxoplasmosis) can have lifelong implications including mental disability and severe eye infections.⁵⁷ Additionally, once a person is infected with *Toxoplasma gondii*, tachyzoites have a propensity for skeletal muscle, which may be relevant for other types of living donations of covered VCAs in the future.⁵⁸

The Workgroup recognized the potential need to make this a required test for all living donors, which fell outside the scope of this project. If the Committee decides to pursue toxoplasma testing for all living donors, it will be part of a future project.

Additional Tests and Medical History for Uterus Donors

The rest of the proposed table is dedicated to uterus-specific tests. These requirements are informed by Workgroup member expertise, IRB protocols of existing uterus programs, clinical literature, and consultation with the DTAC.

⁵⁷ "Toxoplasmosis," *Mayo Clinic*. <https://www.mayoclinic.org/diseases-conditions/toxoplasmosis/symptoms-causes/syc-20356249> (accessed April 2, 2021).

⁵⁸ Montoya, JG and Liesenfeld, O, "Toxoplasmosis," *Lancet*, 2004; 363: 1965-1976. <https://pubmed.ncbi.nlm.nih.gov/15194258/> (accessed April 2, 2021).

The collection of medical history on gynecological and obstetric history, requirement for a pap smear and pelvic exam, and radiological assessment represent the minimum evaluation requirements that were found in uterus program IRB protocols.^{59, 60} As part of the living donor's medical history, the Committee proposes collecting their history of pregnancy and childbirth, since pregnancy and childbirth are the desired outcomes of uterus transplant. Specific data elements related to the collection of this medical history can be found in the VCA Committee's *Modify Data Collection on VCA Living Donors* proposal.⁶¹ The radiological assessment language included in the proposed table is also consistent with existing language for the evaluation of liver donors.⁶²

The required transmissible disease screening requirements for uterus donors are informed by IRB protocols of existing uterus programs and DTAC expertise.^{63, 64} The two workgroups made sure to align the list of required tests within the proposed policy and updates to the LDR form. The required tests are included because positive results could impact the outcome of the uterus transplant and the viability of the fetus.⁶⁵ The proposed testing requirements for living uterus donors are as follows:

- Bacterial Vaginosis (Gardnerella Vaginalis)
- Chlamydia by nucleic acid test (NAT)
- Gonorrhea by nucleic acid test (NAT)
- Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test
- Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA
- Trichomoniasis
- Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)

The DTAC was instrumental in informing the medical evaluation requirements within the proposal. The DTAC submitted a public comment recommending to amend the policy to specify timing requirements for chlamydia, gonorrhea, and trichomoniasis in addition to fungal screening as proposed. Specifically, the DTAC recommended testing for these diseases should occur at both evaluation and recovery. The Committee decided not to add the recommended requirements at this time, but will consider them as part of a future project.

Exclusion Criteria for Living VCA Donors

The Workgroup did discuss whether to add exclusion criteria to *Policy 14* for living donor of covered VCAs. For example, various literature recommends restricting uterus donation to a maximum age.⁶⁶ However, there is a lack of consensus in the community on what the cutoff age should be. Also, current

⁵⁹ Baylor Research Institute, *Uterine Transplantation and Pregnancy Induction in Women affected by Absolute Uterine Factor Infertility (Donor)*, Institutional Review Board Protocols, 2019.

⁶⁰ Brigham and Women's Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

⁶¹ *Briefing to the OPTN Board of Directors on Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf (accessed April 2, 2021).

⁶² OPTN Policy 14.4.C, *Additional Requirements for the Medical Evaluation of Living Liver Donors* (April 26, 2021).

⁶³ Ibid.

⁶⁴ Ibid.

⁶⁵ Ibid.

⁶⁶ Brännström, Mats, et al. "Uterus Transplant: A Rapidly Expanding Field," *Transplantation*, 2018; 102: 569-577. <https://pubmed.ncbi.nlm.nih.gov/29210893/> (accessed April 2, 2021).

OPTN policy does not have a maximum age restriction on the living donation of other organ types. Therefore, the Committee decided to leave that decision to the hospital's internal protocols.⁶⁷ Additionally, the Committee emphasized the proposed policy is not meant to be prescriptive of medical practice but rather establishes policy that provides fundamental safety and protections for living donors. As for other types of VCA transplant, the Workgroup did not believe there was sufficient data and collective experience to recommend any specific exclusion criteria at this time.

Omission from Outcomes Reporting

Current policy includes requirements for programs to provide donors with outcome and survival data under *Table 14-4: Required Recipient Outcome and Transplanted Organ Survival Data*.⁶⁸ The table is specific to outcomes reports developed by the Scientific Registry of Transplant Recipients (SRTR) and the SRTR does not currently track VCA data. Additionally, the OPTN does not currently collect this data. Once VCA data collection is implemented, it would take considerable time for there to be enough outcomes data to inform the SRTR outcomes model and reports VCA programs would need to comply with the policy. Also, graft survival data would not be an appropriate metric for some types of VCA. For example, uterus transplants are temporary transplants in nature as they are removed after childbirth. Therefore, VCA donations are excluded from the requirement at this time.

For more information on the VCA Committee's work on evaluating data collection for uterus recipients and their children, see the *Update to VCA Transplant Outcomes Data Collection* proposal and *Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients* request for feedback from January 2020 Public Comment.^{69, 70}

Prior Living Donor Priority

Following Public Comment, the Committee considered whether a living VCA donor should receive prior living donor priority for kidneys. This subject also falls outside of the scope of this proposal and the Committee will consider this topic in future discussions.

Collaboration with VCA Committee

As previously stated, this proposal was developed in conjunction with a data collection proposal from the VCA Committee. The *Modify Data Collection on VCA Living Donors* proposal would add data submission requirements for VCA to *Policy 18: Data Collection Requirements* and add VCA and uterus

⁶⁷ Meeting Summary for April 8, 2020 meeting, OPTN Living Donor VCA Workgroup, https://optn.transplant.hrsa.gov/media/3742/20200408_living-donor_vca-workgroup_meeting-summary.pdf (accessed April 2, 2021).

⁶⁸ OPTN Policy 14.4, *Requirements for the Medical Evaluation of Living Donors* (April 26, 2021).

⁶⁹ *Update to VCA Transplant Outcomes Data Collection*, OPTN VCA Committee, January 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/update-to-vca-transplant-outcomes-data-collection/> (accessed April 2, 2021).

⁷⁰ *Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients*, OPTN VCA Committee, January 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/measuring-transplant-outcomes-by-collecting-data-on-children-born-to-uterus-recipients/> (accessed April 2, 2021).

specific elements to the LDR and LDF forms.⁷¹ The Living Donor and VCA Committees ensured alignment between the medical evaluation testing requirements and the data fields being added to the LDR.

The VCA Committee’s proposal has a delayed implementation timeline due to UNetSM programming needs. For this reason, changes to *Policy 14.5.C: Reporting of Living Donor Blood Type and Subtype* can be found in the VCA Committee’s proposal as they will require UNet implementation.

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) directed the OPTN to exercise oversight over living donation.⁷²

“Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN “to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule.”⁷³

In 2014, the OPTN Final Rule was amended by the Secretary of the U.S. Department of Health and Human Services (HHS) to include vascularized composite allografts (VCAs) as “covered human organs”.⁷⁴ This proposal is consistent with the OPTN’s responsibility to continue to develop living donor policies regarding living VCA donors and recipients of living VCA donors. This proposal establishes safeguards and compliance standards for living VCA donor programs.

Recommendations for testing of living VCA donors, including the specific tests for living uterus donors, are presented under the authority of 121.4(a)(2), which requires the OPTN to create policies that are “consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases”.⁷⁵ The CDC has not issued recommendations on this type of testing so the Committee relied on evidence in literature, existing IRB protocols, and consultation with the DTAC to support the proposed testing policies.^{76,77,78,79}

⁷¹ *Briefing to the OPTN Board of Directors on Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf (accessed April 2, 2021).

⁷² Department of Health and Human Services, Health Resources and Services Administration, “Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines,” 71 Fed. Reg. 34946 No. 116 (June 16, 2006). <https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-and-transplantation-network-optn-living-donor> (accessed April 2, 2021).

⁷³ Ibid.

⁷⁴ Department of Health and Human Services, Final rule, “Organ Procurement and Transplantation Network, 42 CFR Part 121,” *Federal Register* 78, No. 128 (July 3, 2013). <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf> (accessed April 2, 2021).

⁷⁵ 42 CFR §121.4(a)(2)

⁷⁶ “Toxoplasmosis,” *Mayo Clinic*. <https://www.mayoclinic.org/diseases-conditions/toxoplasmosis/symptoms-causes/syc-20356249> (accessed April 2, 2021).

⁷⁷ Montoya, JG and Liesenfeld, O, “Toxoplasmosis,” *Lancet*, 2004; 363: 1965-1976. <https://pubmed.ncbi.nlm.nih.gov/15194258/> (accessed April 2, 2021).

⁷⁸ Baylor Research Institute, *Uterine Transplantation and Pregnancy Induction in Women affected by Absolute Uterine Factor Infertility (Donor)*, Institutional Review Board Protocols, 2019.

⁷⁹ Brigham and Women’s Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

Alignment with OPTN Strategic Plan⁸⁰

Improve waitlisted patient, living donor, and transplant recipient outcomes:

Providing informed consent and requiring medical tests specific to VCA will improve both the living donor and the recipient's outcomes. Furthermore, the medical evaluation policy requirements along with the corresponding data collection in the VCA Committee's proposal will identify trends related to living donor and transplant recipient outcomes to inform future policy development intended to promote patient safety.

Promote living donor and transplant recipient safety:

The proposed policy requirements intend to establish policy that provide fundamental safety and protections for living VCA donors.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

VCA-specific transplant programs and recovery hospitals will need to become familiar with OPTN policy for living donors. Administrative staff will need to become familiar with the new types of living organ donors that would be covered by the revised policy. This proposal may add additional administrative burden for programs, to adapt protocols to include the informed consent and medical evaluation requirements related to VCA, particularly uterus transplantation. However, these VCA-specific protocols should be similar to evaluations currently done for other living donor types with some unique elements for VCA donors. Staff training and education will be necessary to implement and administer the new requirements for VCA living donor programs.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Operations affecting the OPTN

This proposal will not require programming. Communication will be necessary and determined following public comment.

⁸⁰ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

Projected Fiscal Impact

Projected Impact on Transplant Hospitals

The time and cost to implement these changes at transplant hospitals are minimal. Protocol development and implementation will require time of existing staff. Staff administer these processes for other organ programs presently.

Time for centers to create protocols for psychosocial evaluation would need to be developed with the guidelines outlined in the policy. Creating protocols for informed consent, psychosocial evaluation, and medical evaluation requirements should be similar to evaluations presently conducted for living donors with some unique elements for VCA donors, specifically uterus donors. Staff training and education will be necessary to implement and administer the informed consent process and psychosocial evaluation that will be required for VCA living donors.

The OPTN Fiscal Impact Group advised the burden of this work can be absorbed with current staff, but may increase if VCA programs grow in volume. VCA programs are still smaller in size/volume compared to other organ programs. Implementation is estimated at one to three months, but may be longer depending on the time needed to develop a VCA-specific protocol.

Projected Impact on the OPTN

The Policy and Community Relations (PCR) department hosted a workgroup to review *OPTN Policy 14: Living Donation* and develop requirements for living VCA donation, particularly for informed consent and medical evaluations. The PCR team worked closely with Member Quality and other UNOS departments to consult in internal and committee meetings.

A Small OPTN implementation effort, estimated at 340 hours, includes updating Member Quality processes for monitoring and training staff, as well as offerings from Professional Education and Communications to educate members about the policy changes. No IT implementation is required.

A Very Small ongoing effort, estimated at 60 hours, is anticipated for Member Quality to monitor VCA transplant programs performing living donor recoveries; for Research and PCR to prepare and review monitoring reports; and for the Organ Center to answer member questions.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on OPOs.

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current OPTN monitoring processes for living donor recovery hospitals. Site surveyors will continue to review living donor medical records and hospital policies and

protocols, as well as interview hospital staff to verify that living donors are evaluated and consented according to OPTN policy requirements and the hospital's own policies and protocols.

Policy Evaluation

The following metrics, and any others subsequently requested by the Committee, will be monitored to evaluate the effect of the policy approximately 6 months after implementation, and as needed thereafter.

- The number of living VCA donors by VCA type
- The number of living donor events (required reporting under *Policy 18.6*) reported for living VCA donors
- LDR and LDF data submission for living VCA donors will also be monitored, as the complementary proposal *Modify Data Collection on Living VCA Donors* will impact LDR/LDF data collection for these donors

Conclusion

This proposal would update *Policy 14: Living Donation* to cover all living donors and by default add living donors of covered VCAs to living donor policy as well as add unique informed consent and medical evaluation requirements for living VCA donors. These changes are being proposed to promote patient safety in an evolving field. The new policy requirements would establish safeguards and compliance standards for living VCA donor programs. This proposal was developed in conjunction with a related proposal, *Modify Data Collection on VCA Living Donors*, which was also released for public comment in August 2020.⁸¹ The *Modify Data Collection on VCA Living Donors* proposal would add data submission requirements for VCA to *Policy 18: Data Collection Requirements* and add VCA and uterus specific elements to the LDR and LDF forms. The Living Donor and VCA Committees ensured alignment between the medical evaluation testing requirements and the data fields being added to the required forms.

⁸¹ *Briefing to the OPTN Board of Directors on Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, December 2020, https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf (accessed April 2, 2021).

Policy Language

1 **RESOLVED**, that the creation of **Policy 14.4.D: Additional Requirements for the Medical Evaluation of**
 2 **Living Donors of Covered VCAs**, as well as the changes to **Policies 14.1.A: Living Donor Psychosocial**
 3 **Evaluation Requirements, 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals, 14.3:**
 4 **Informed Consent Requirements, and 14.4.A: Living Donor Medical Evaluation Requirements**, as set
 5 forth below, are hereby approved, effective September 1, 2021.

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

6 **14.1 Psychosocial Evaluation Requirements for Living Donors**

7 **14.1.A Living Donor Psychosocial Evaluation Requirements**

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

10
 11 The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist,
 12 masters prepared social worker, or licensed clinical social worker prior to organ recovery.
 13 Documentation of the psychosocial evaluation must be maintained in the living donor medical
 14 record and include *all* of the following components:

- 15
- 16 1. An evaluation for any psychosocial issues, including mental health issues, that might
 17 complicate the living donor's recovery and could be identified as risks for poor psychosocial
 18 outcome.
- 19 2. An evaluation for the presence of behaviors that may increase risk for disease transmission
 20 as defined by the *U.S. Public Health Service (PHS) Guideline*.
- 21 3. A review of the living donor's history of smoking, alcohol, and drug use, including past or
 22 present substance abuse disorder.
- 23 4. The identification of factors that warrant educational or therapeutic intervention prior to
 24 the final donation decision.
- 25 5. The determination that the living donor understands the short and long-term medical and
 26 psychosocial risks for both the living donor and recipient associated with living donation.
- 27 6. An assessment of whether the decision to donate is free of inducement, coercion, and other
 28 undue pressure by exploring the reasons for donating and the nature of the relationship, if
 29 any, to the transplant candidate.
- 30 7. An assessment of the living donor's ability to make an informed decision and the ability to
 31 cope with the major surgery and related stress. This includes evaluating whether the donor
 32 has a realistic plan for donation and recovery, with social, emotional and financial support
 33 available as recommended.
- 34 8. A review of the living donor's occupation, employment status, health insurance status, living
 35 arrangements, and social support.
- 36 9. The determination that the living donor understands the potential financial implications of
 37 living donation.
- 38

39 14.2 Independent Living Donor Advocate (ILDA) Requirements

40 14.2.A ILDA Requirements for Living Donor Recovery Hospitals

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

43
44 For any living donor who is undergoing evaluation for donation, the living donor recovery
45 hospital must designate and provide each living donor with an ILDA who is not involved with the
46 potential recipient evaluation and is independent of the decision to transplant the potential
47 recipient. The ILDA may be one person or an ILDA team with multiple members. An ILDA team
48 must designate one person from the team as the key contact for each living donor. All ILDA
49 requirements must be completed prior to organ recovery.

50
51 The ILDA must:

- 52
- 53 1. Function independently from the transplant candidate's team.
- 54 2. Advocate for the rights of the living donor.
- 55 3. Fulfill the qualification and training requirements specified in the recovery hospital's
56 protocols regarding knowledge of living organ donation, transplantation, medical ethics,
57 informed consent, and the potential impact of family or other external pressure on the living
58 donor's decision about whether to donate.
- 59 4. Review and document whether the living donor has received information on each of the
60 following areas and assist the donor in obtaining additional information from other
61 professionals as needed about the:
 - 62 a. Informed consent process as described in *Policy 14.3: Informed Consent*
63 *Requirements*
 - 64 b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation*
65 *Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
 - 66 c. Surgical procedure
 - 67 d. Follow-up requirements, and the benefit and need for participating in recovery
68 hospital's requirements according to *Policies 18.1: Data Submission Requirements,*
69 *18.5: Living Donor Data Submission Requirements, and 18.6: Reporting of Living*
70 *Donor Adverse Events*
 - 71

72 14.3 Informed Consent Requirements

73 The living donor recovery hospital is responsible for obtaining and documenting informed consent prior
74 to organ recovery. Informed consent requirements ~~apply to living kidney, liver, pancreas, intestine, and~~
75 ~~lung donors and~~ must include *all* of the components in *Tables 14-1* through *14-5*. Documentation of
76 informed consent must be maintained in the living donor medical record.
77

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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>

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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.

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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

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14.4 Medical Evaluation Requirements for Living Donors

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14.4.A Living Donor Medical Evaluation Requirements

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

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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.

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

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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 <i>all</i> 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 <i>all</i> 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>

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