

*Public Comment Proposal*

# 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: Psychosocial Evaluation Requirements for Living Donors</p> <p>14.2: Independent Living Donor Advocate (ILDA) Requirements</p> <p>14.3: Informed Consent Requirements</p> <p>14.4: Medical Evaluation Requirements for Living Donors</p> <p>14.5: Living Donor Blood Type Determination and Reporting</p> <p>14.6: Placement of Living Donor Organs</p> <p>14.7: Living Donor Pre-Recovery Verification</p> <p>14.9: Requirements for Domino Donors and Non-Domino Therapeutic Donors</p>
<i>Sponsoring Committee:</i>	Living Donor Committee
<i>Public Comment Period:</i>	August 4, 2020 – October 1, 2020

## 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 cover living VCA donation. The purpose of this proposal is to establish safeguards 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 VCA 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 VCA, 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. This proposal was developed in conjunction with the VCA Committee's related proposal, *Modify Data Collection on VCA Living Donors*, which is also being released for public comment in August 2020.<sup>1</sup>

The Committee is seeking public feedback on the proposed informed consent and medical evaluation tables for living VCA donors. The Committee would like to know if the proposed language is sufficiently clear enough to be incorporated into hospital protocol. Additionally, the Committee would appreciate feedback on the specific requirements that are included in the proposed language.

<sup>1</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

## 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 covered by 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.<sup>2</sup>

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.<sup>3</sup> With that directive, the OPTN was charged with the oversight of VCA procurement and transplantation. In 2014 the OPTN Board of Directors made VCA an organ type recognized by the OPTN.<sup>4</sup>

With the incorporation of VCA as an organ type recognized by 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.<sup>5</sup> The Committee was cautious of the risks associated with including all living donors as this meant there may be insufficient guardrails or listed procedures for living VCA donors. In response, the Committee decided to revise living donor policies to specifically name organs by type: liver, kidney, lung, pancreas, and intestine.<sup>6</sup> 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.<sup>7</sup>

In 2015, the Living Donor, VCA, and Ethics Committees formed a workgroup to develop the guidance document, *VCAs from Living Donors*.<sup>8</sup> 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

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<sup>2</sup> *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](https://optn.transplant.hrsa.gov/media/1451/pubcommentprosub_337.pdf) (accessed June 15, 2020).

<sup>3</sup> 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 June 15, 2020).

<sup>4</sup> 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](https://optn.transplant.hrsa.gov/media/1279/policynotice_20140701.pdf) (accessed June 25, 2020).

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

<sup>7</sup> OPTN Policy 14, *Living Donation*, (June 8, 2020).

<sup>8</sup> *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 June 15, 2020).

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.”<sup>9</sup>*

The field of VCA transplantation was introduced in 1998 following the first hand transplant in France.<sup>10</sup> 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”.<sup>11</sup> Since 1998, there have been several living donor restorative VCA transplants. One example of this in the U.S. was a case in 2008 where abdominal wall tissue was transplanted between twin sisters for breast reconstruction following mastectomy.<sup>12</sup>

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.<sup>13</sup> In 2016, the first U.S. uterus transplant was performed at the Cleveland Clinic.<sup>14</sup> Between September 2016 and May 2020 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.

<sup>9</sup> 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 June 15, 2020).

<sup>10</sup> 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 June 15, 2020).

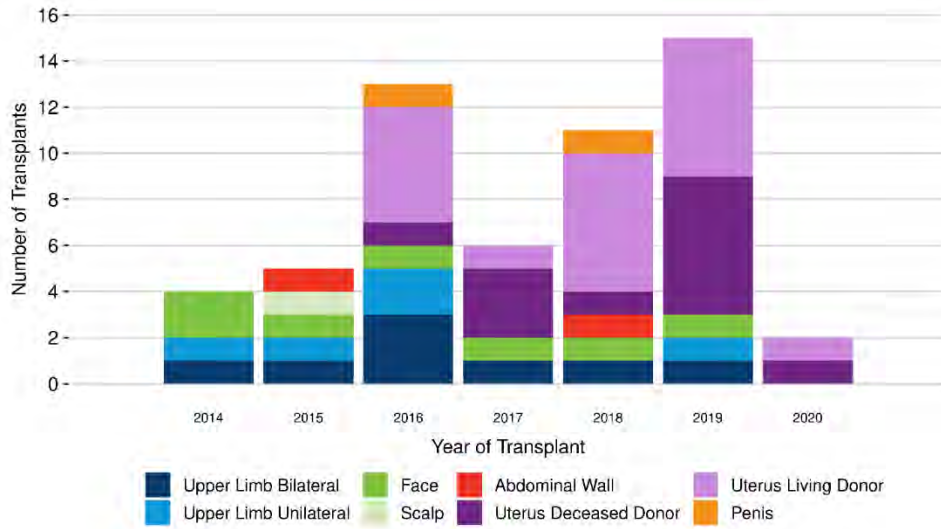
<sup>11</sup> Ibid.

<sup>12</sup> Allen, R.J., et al., “Transplantation in Identical Twins: Another Option for Breast Reconstruction,” *Plastic and Reconstructive Surgery*, 2008; 122: 1019-1023. [https://journals.lww.com/plasreconsurg/Abstract/2008/10000/Transplantation\\_in\\_Identical\\_Twins\\_\\_Another\\_Option.3.aspx](https://journals.lww.com/plasreconsurg/Abstract/2008/10000/Transplantation_in_Identical_Twins__Another_Option.3.aspx) (accessed June 15, 2020).

<sup>13</sup> 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 June 15, 2020).

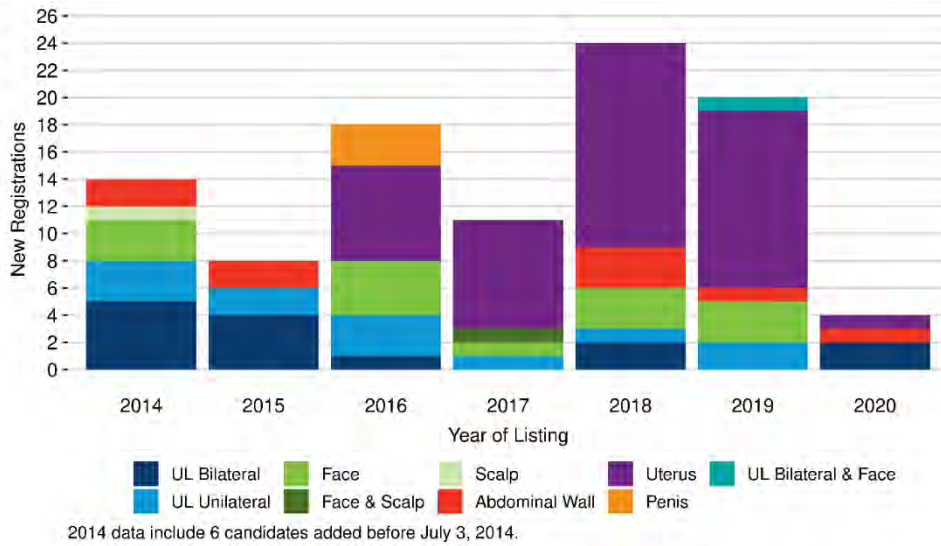
<sup>14</sup> “Cleveland Clinic Performs First Uterine Transplant in U.S.,” *Cleveland Clinic*, February 26, 2016. <https://consultqd.clevelandclinic.org/cleveland-clinic-performs-first-uterine-transplantation/> (accessed June 15, 2020).

**Figure 1: VCA Transplants in the U.S.: July 4, 2014 – June 3, 2020**



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.<sup>15</sup>

**Figure 2: VCA Waitlist Additions by Organ and Year: 2014 – 2020**



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

<sup>15</sup> 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 June 15, 2020).

accordance with section 121.8 of the final rule”.<sup>16</sup> As VCAs are organs, the OPTN has the authority and responsibility to develop policies regarding living VCA donors and recipients of living VCA donor organs. 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.”<sup>17</sup> 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 VCA donors. Various literature have also stressed the importance for the OPTN to develop formal policies and data submission requirements on live uterus donation.<sup>18, 19, 20</sup>

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.<sup>21</sup> Some members served on both workgroups simultaneously and these proposals are designed to complement each other.

## 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.

This proposal aligns with two goals of the OPTN Strategic Plan: “improve waitlisted patient, living donor, and transplant recipient outcomes” and “to promote living donor and transplant recipient safety.”<sup>22</sup> For patient safety, and to allow the policy to grow with the future evolution of the VCA field, the policy is

<sup>16</sup> 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 June 23, 2020).

<sup>17</sup> OPTN Strategic Plan, 2018-2021, [https://optn.transplant.hrsa.gov/media/2392/executive\\_publiccomment\\_strategicplan\\_20180122.pdf](https://optn.transplant.hrsa.gov/media/2392/executive_publiccomment_strategicplan_20180122.pdf) (accessed June 25, 2020).

<sup>18</sup> *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 June 15, 2020).

<sup>19</sup> 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 June 15, 2020).

<sup>20</sup> 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 June 15, 2020).

<sup>21</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

<sup>22</sup> Ibid.

being expanded to cover all living donors. The purpose of this proposal is to establish safeguards and compliance standards for living VCA donor programs.

## Overview of Proposal

The proposal is to revise living donor policies to make them applicable to all living donors. Additionally, the proposal would add living VCA donation-specific elements 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 VCA donors.<sup>23</sup>

## 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. "Living donor" is defined in OPTN policy as "a living individual from whom at least one organ is recovered for transplantation".<sup>24</sup> 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.""*<sup>25</sup>

## Informed Consent

Current policy includes general informed consent requirements under *Table 14-1: Requirements for Living Donor Informed Consent* for all covered living donors.<sup>26</sup> 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 VCA donors. The proposed elements are summarized in **Table 1**.

<sup>23</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

<sup>24</sup> OPTN Policy 1.2, *Definitions* (June 8, 2020).

<sup>25</sup> OPTN Final Rule, 42 CFR § 121.2 (July 20, 2020).

<sup>26</sup> OPTN Policy 14.3, *Informed Consent Requirements* (June 8, 2020).

**Table 1: Additional Requirements for the Informed Consent of Living VCA Donors**

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:
<p><b>Disclose to all living non-genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions</b></p>	<p>There are surgical, psychosocial, and financial risks associated with living non-genitourinary VCA donation, 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"> <li>• Potential surgical risks:               <ul style="list-style-type: none"> <li>• Loss of function</li> <li>• Physical disability</li> <li>• Physical disfigurement</li> </ul> </li> <li>• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome</li> <li>• Potential financial impacts: Procedure may not be covered by health insurance</li> </ul>
<p><b>Disclose to all living genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions</b></p>	<p>There are surgical, psychosocial, and financial risks associated with living genitourinary VCA donation, 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"> <li>• Potential surgical risks:               <ul style="list-style-type: none"> <li>• Bowel injury</li> <li>• Decreased fertility (male)</li> <li>• Inability to bear children (female)</li> <li>• Loss of function</li> <li>• Need for hormonal replacement therapy</li> <li>• Pain or discomfort with intercourse</li> <li>• Physical disfigurement (male)</li> <li>• Urinary tract injury or dysfunction</li> </ul> </li> <li>• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome</li> <li>• Potential financial impacts: Procedure may not be covered by health insurance</li> </ul>

The table divides living VCA donors into two categories: non-genitourinary and genitourinary. In early drafting, the table distinguished between living non-reproductive and reproductive VCA donors. However, the updated definition of VCA (to be implemented in OPTN policy in 2021) includes a list of VCA organs as follows:<sup>27</sup>

- Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap)

<sup>27</sup> Executive Summary for June 6-7, 2016, OPTN Board of Directors Meeting, [https://optn.transplant.hrsa.gov/media/1953/executive\\_summary\\_06-2016.pdf](https://optn.transplant.hrsa.gov/media/1953/executive_summary_06-2016.pdf) (accessed June 15, 2020).



- Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid)
- Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis)
- Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)
- Glands (including, but not limited to adrenal or thymus)
- Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior lateral thigh flaps, or toe transfers)
- Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap)
- Spleen

The language was changed to non-genitourinary and genitourinary to match language in the new definition of VCA.<sup>28</sup> Tying this language to the definition of VCA in *OPTN Policy 1* would also ensure the policy is aligned with the definition of VCA if it were to be 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.

### *Potential Surgical Risks*

The largest differences between the non-genitourinary and genitourinary 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 genitourinary category as well.

For the genitourinary 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 reproductive organ donation (ex. testicular transplant).<sup>29, 30</sup> Therefore, the list of potential surgical risks for genitourinary organ donation was amended to include:

<sup>28</sup> 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 June 15, 2020).

<sup>29</sup> Ibid.

<sup>30</sup> 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 June 15, 2020).

- 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

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.<sup>31</sup> These risks were informed by the clinical expertise of Workgroup members, existing literature, as well as IRB protocols of existing uterus transplant programs.<sup>32, 33, 34, 35, 36, 37, 38, 39, 40</sup>

### *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”.<sup>41</sup> The Workgroup discussed editing this requirement, as VCA transplant doesn’t 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 successful not only by the organ’s function, but by the delivery of a healthy child.<sup>42</sup> A donation of this nature could have unique psychological meaning for the donor.<sup>43, 44, 45</sup> Therefore, the Workgroup

<sup>31</sup> 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 June 15, 2020).

<sup>32</sup> Baylor Research Institute, *Uterine Transplantation and Pregnancy Induction in Women affected by Absolute Uterine Factor Infertility (Donor)*, Institutional Review Board Protocols, 2019.

<sup>33</sup> Brigham and Women’s Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

<sup>34</sup> 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 June 15, 2020).

<sup>35</sup> Brännström, Mats, et al. “Uterus Transplant: A Rapidly Expanding Field,” *Transplantation*, 2018; 102: 569-577. <https://pubmed.ncbi.nlm.nih.gov/29210893/> (accessed June 15, 2020).

<sup>36</sup> 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 June 15, 2020).

<sup>37</sup> 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 June 15, 2020).

<sup>38</sup> 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 June 15, 2020).

<sup>39</sup> 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 June 15, 2020).

<sup>40</sup> 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 June 15, 2020).

<sup>41</sup> OPTN Policy 14.3, *Informed Consent Requirements* (June 8, 2020).

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

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 non-genitourinary and genitourinary VCA organs as follows:<sup>46,47</sup>

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

### *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”.<sup>48</sup> 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.<sup>49</sup> The proposed table includes language to highlight this additional risk for living VCA donors.<sup>50</sup>

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

The Committee is seeking public feedback on the proposed Additional Requirements for the Informed Consent of Living VCA Donors table (**Table 1**):

- Is the policy language sufficiently clear enough to be incorporated into hospital protocol?
- Do you agree with the potential surgical risks for genitourinary and non-genitourinary donors?
- Do you agree with the potential psychosocial and financial risks for genitourinary and non-genitourinary donors?
- Are there other VCA-specific or uterine-specific surgical, psychosocial, or financial risks the Committee should consider incorporating into the table?

<sup>46</sup> 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 June 15, 2020).

<sup>47</sup> 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 June 15, 2020).

<sup>48</sup> OPTN Policy 14.3, *Informed Consent Requirements* (June 8, 2020).

<sup>49</sup> 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 June 15, 2020).

<sup>50</sup> Brigham and Women’s Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

## Medical Evaluation Requirements

Current policy includes medical evaluation requirements under *Table 14-5: Requirements for Living Donor Medical Evaluations* for all covered living donors.<sup>51</sup> 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 VCA donors. Most of the proposed elements are specific to living uterus donors, but there is one required test that would apply to all VCA donors. The proposed elements are summarized in **Table 2**.

**Table 2: Additional Requirements for the Medical Evaluation of Living VCA Donors**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Transmissible disease screening for all VCA donors</b>	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"> <li>• Toxoplasma Immunoglobulin G (IgG) antibody test</li> </ul>
<b>Additional Specific medical history for uterus donors</b>	<ul style="list-style-type: none"> <li>• Gynecological and obstetric history including prior childbirth</li> </ul>
<b>Additional Specific tests for uterus donors</b>	<ul style="list-style-type: none"> <li>• Pap smear</li> </ul>
<b>Additional anatomic assessment for uterus donors</b>	<ul style="list-style-type: none"> <li>• Pelvic exam</li> <li>• A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation</li> </ul>

<sup>51</sup> OPTN Policy 14.4, *Medical Evaluation Requirements for Living Donors* (June 8, 2020).

This evaluation must be completed:	Including evaluation for and assessment of this information:
<p><b>Additional transmissible disease screening for uterus donors</b></p>	<p>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:</p> <ul style="list-style-type: none"> <li>• Bacterial Vaginosis (Gardnerella Vaginalis)</li> <li>• Chlamydia by nucleic acid test (NAT)</li> <li>• Gonorrhea by nucleic acid test (NAT)</li> <li>• Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test</li> <li>• Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA</li> <li>• Trichomoniasis</li> <li>• Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)</li> </ul>

### *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 DTAC recommended adding this test as a requirement for VCA living donors 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.<sup>52</sup> 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 VCA donations in the future.<sup>53</sup> The Workgroup recognized the potential need to make this a required test for all living donors, but that fell outside the scope of this project, which was focused on VCA living donation.

The Committee is seeking public feedback on the proposed toxoplasma requirement included in the table (**Table 2**):

- Should toxoplasma be a required test for all living donors?

### *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 OPTN Disease Transmission Advisory Committee (DTAC).

<sup>52</sup> "Toxoplasmosis," *Mayo Clinic*. <https://www.mayoclinic.org/diseases-conditions/toxoplasmosis/symptoms-causes/syc-20356249> (accessed June 15, 2020).

<sup>53</sup> Montoya, JG and Liesenfeld, O, "Toxoplasmosis," *Lancet*, 2004; 363: 1965-1976. <https://pubmed.ncbi.nlm.nih.gov/15194258/> (accessed June 15, 2020).

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.<sup>54, 55</sup> 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.<sup>56</sup> The radiological assessment language included in the proposed table is also consistent with existing language for the evaluation of liver donors.<sup>57</sup>

The required transmissible disease screening requirements for uterus donors are informed by IRB protocols of existing uterus programs and DTAC expertise.<sup>58, 59</sup> 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.<sup>60</sup> 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 Committee is seeking public feedback on the proposed Additional Requirements for the Medical Evaluation of Living VCA Donors table (**Table 2**):

- Is the policy language sufficiently clear enough to be incorporated into hospital protocol?
- Do you agree with the uterine-specific evaluations and tests required in the table?
- Are there other VCA-specific or uterine-specific evaluations or tests the Committee should consider incorporating into the table?

### *Exclusion Criteria for Living VCA Donors*

The Workgroup did discuss whether to add living VCA donor exclusion criteria to *Policy 14*. For example, various literature recommends restricting uterus donation to a maximum age.<sup>61</sup> However, there is a lack of consensus in the community on what the cutoff age should be. Also, current OPTN policy does not

<sup>54</sup> Baylor Research Institute, *Uterine Transplantation and Pregnancy Induction in Women affected by Absolute Uterine Factor Infertility (Donor)*, Institutional Review Board Protocols, 2019.

<sup>55</sup> Brigham and Women's Hospital, *Uterine Transplant in Absolute Uterine Infertility (AUIF)*, Institutional Review Board Protocols, 2016.

<sup>56</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

<sup>57</sup> OPTN Policy 14.4.C, *Additional Requirements for the Medical Evaluation of Living Liver Donors* (June 8, 2020).

<sup>58</sup> *Ibid.*

<sup>59</sup> *Ibid.*

<sup>60</sup> *Ibid.*

<sup>61</sup> Brännström, Mats, et al. "Uterus Transplant: A Rapidly Expanding Field," *Transplantation*, 2018; 102: 569-577. <https://pubmed.ncbi.nlm.nih.gov/29210893/> (accessed June 15, 2020).

have a maximum age restriction on the living donation of other organ types. Therefore, the Workgroup decided to leave that decision to the hospital's internal protocols.<sup>62</sup> 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*.<sup>63</sup> 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.<sup>64, 65</sup>

## 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 specific elements to the LDR and LDF forms.<sup>66</sup> 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 UNet<sup>SM</sup> 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.

<sup>62</sup> 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](https://optn.transplant.hrsa.gov/media/3742/20200408_living-donor_vca-workgroup_meeting-summary.pdf) (accessed June 15, 2020).

<sup>63</sup> OPTN Policy 14.4, *Requirements for the Medical Evaluation of Living Donors* (June 8, 2020).

<sup>64</sup> *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/>

<sup>65</sup> *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/>

<sup>66</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

## NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) stated that the oversight of living donation of all types falls under the authority of the OPTN.<sup>67</sup>

*“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.”<sup>68</sup>*

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”.<sup>69</sup> 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.

## Implementation Considerations

### Member and OPTN Operations

#### *Operations affecting Transplant Hospitals*

VCA-specific transplant programs 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 the OPTN*

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

#### *Operations affecting Histocompatibility Laboratories*

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

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<sup>67</sup> 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 June 23, 2020).

<sup>68</sup> Ibid.

<sup>69</sup> 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 June 15, 2020).



## *Operations affecting Organ Procurement Organizations*

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

## Potential Impact on Select Patient Populations

This proposal aims to protect the safety of living VCA donors by including them in living donor policy, ensuring member compliance with policy requirements. The primary impact of this proposal will be on transplant hospitals with approved VCA programs.

## 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 administers 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.

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*

Preliminary estimates indicate that this would be a small project for the OPTN to implement. The OPTN estimates approximately 250 hours may be needed for Member Quality monitoring plan updates and developing post-implementation review plans.

### *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, and 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 VCA organs 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 is also being released for public comment in August 2020.<sup>70</sup> 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.

The Committee is seeking feedback on the following questions:

The Committee is seeking public feedback on the proposed Additional Requirements for the Informed Consent of Living VCA Donors (**Table 1**) and Additional Requirements for the Medical Evaluation of Living VCA Donors tables (**Table 2**):

- Is the proposed policy language sufficiently clear enough to be incorporated into hospital protocol?
- Do you agree with the potential surgical risks for genitourinary and non-genitourinary donors in **Table 1**?

<sup>70</sup> *Modify Data Collection on VCA Living Donors*, OPTN VCA Committee, August 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/>

- Do you agree with the potential psychosocial and financial risks for genitourinary and non-genitourinary donors in **Table 1**?
- Are there other VCA-specific or uterine-specific surgical, psychosocial, or financial risks the Committee should consider incorporating into the table?
- Do you agree with the uterine-specific evaluations and tests required in **Table 2**?
- Are there other VCA-specific or uterine-specific evaluations or tests the Committee should consider incorporating into the table?
- Should toxoplasma be a required test for all living donors?

## Policy Language

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.

### 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.~~

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

45  
 46 The ILDA must:

- 47
- 48 1. Function independently from the transplant candidate's team.
  - 49 2. Advocate for the rights of the living donor.
  - 50 3. Fulfill the qualification and training requirements specified in the recovery hospital's  
 51 protocols regarding knowledge of living organ donation, transplantation, medical ethics,  
 52 informed consent, and the potential impact of family or other external pressure on the living  
 53 donor's decision about whether to donate.
  - 54 4. Review and document whether the living donor has received information on each of the  
 55 following areas and assist the donor in obtaining additional information from other  
 56 professionals as needed about the:
    - 57 a. Informed consent process as described in *Policy 14.3: Informed Consent*  
 58 *Requirements*
    - 59 b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation*  
 60 *Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
    - 61 c. Surgical procedure
    - 62 d. Follow-up requirements, and the benefit and need for participating in recovery  
 63 hospital's requirements according to *Policies 18.1: Data Submission Requirements*,  
 64 *18.5: Living Donor Data Submission Requirements*, and *18.6: Reporting of Living*  
 65 *Donor Adverse Events*

#### 66 **14.2.B ILDA Protocols for Living Donor Recovery Hospitals**

67  
 68 The living donor recovery hospital must develop, and once developed must comply with, written  
 69 protocols for:

- 70
- 71 1. The composition of the ILDA team, if the hospital uses a team.
  - 72 2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum  
 73 qualifications must include knowledge of living organ donation, transplantation, medical  
 74 ethics, informed consent, and the potential impact of family or other external pressures on  
 75 the potential living donor's donation decision. Document that each requirement has been  
 76 met.
  - 77 3. The duties and responsibilities of the ILDA, which must include at least the functions and  
 78 duties according to *Policy 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals*.
  - 79 4. The process the living donor recovery hospital will provide for the ILDA to file a grievance  
 80 when necessary to protect the rights or best interests of the living donor.
  - 81 5. The process the living donor recovery hospital will use to address any grievance raised by  
 82 the ILDA concerning the rights or best interests of the living donor.
- 83

## 84 14.3 Informed Consent Requirements

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

89  
 90

**Table 14-1: Requirements for Living Donor Informed Consent**

The recovery hospital must:	These elements of informed consent :
<b>Obtain from living donors</b>	The living donor’s signature on a document that confirms that the donor: <ol style="list-style-type: none"> <li>1. Is willing to donate</li> <li>2. Is free from inducement and coercion</li> <li>3. Has been informed that he or she may decline to donate at any time</li> </ol>
<b>Provide to living donors</b>	<ol style="list-style-type: none"> <li>1. An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential.</li> <li>2. The ILDA must be available to assist the living donor during the consent process, according to <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i>.</li> <li>3. Instruction about all phases of the living donation process, which includes:               <ul style="list-style-type: none"> <li>• Consent</li> <li>• Medical and psychosocial evaluations</li> <li>• Pre- and post-operative care</li> <li>• Required post-operative follow-up according to <i>Policy 18.5: Living Donor Data Submission Requirements</i>.</li> </ul> </li> </ol> <p>Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital’s staff.</p>

<p><b>Disclose to living donors</b></p>	<ol style="list-style-type: none"> <li>1. It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.</li> <li>2. The recovery hospital must provide an ILDA.</li> <li>3. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation.</li> <li>4. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor’s evaluation or the living donor transplant occurs.</li> <li>5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment.</li> <li>6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient.</li> <li>7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:             <ul style="list-style-type: none"> <li>• Exceed local or national averages</li> <li>• Do not necessarily prohibit transplantation</li> <li>• Are not disclosed to the living donor</li> </ul> </li> <li>8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including:             <ul style="list-style-type: none"> <li>• The reasons for a transplant candidate’s increased likelihood of adverse outcomes</li> <li>• Personal health information collected during the transplant candidate’s evaluation, which is confidential and protected under privacy law</li> </ul> </li> <li>9. Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities.</li> <li>10. The recovery hospital is required to:             <ol style="list-style-type: none"> <li>a. Report living donor follow-up information, at the time intervals specified in <i>Policy 18.5: Living Donor Data Submission Requirements</i>.</li> <li>b. Have the donor commit to post donation follow-up testing coordinated by the recovery hospital.</li> </ol> </li> <li>11. Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor’s first two years of follow-up care:             <ol style="list-style-type: none"> <li>a. May need to be reported to local, state or federal public health authorities</li> <li>b. Will be disclosed to their recipient’s transplant hospital</li> <li>c. Will be reported through the OPTN Improving Patient Safety Portal</li> </ol> </li> <li>12. A living donor must undergo a medical evaluation according to <u><i>Policy 14.4: Medical Evaluation Requirements for Living Donors</i></u> and a psychosocial evaluation as required by <i>Policy 14.1: Psychosocial Evaluation Requirements for Living Donors</i>.</li> <li>13. The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria.</li> <li>14. The following are inherent risks associated with evaluation for living donation:             <ol style="list-style-type: none"> <li>a. Allergic reactions to contrast</li> <li>b. Discovery of reportable infections</li> </ol> </li> </ol>
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The recovery hospital must:	These elements of informed consent :
	<ul style="list-style-type: none"> <li>c. Discovery of serious medical conditions</li> <li>d. Discovery of adverse genetic findings unknown to the living donor</li> <li>e. Discovery of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team</li> </ul> <p>15. There are surgical, medical, psychosocial, and financial risks associated with living donation, 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"> <li>a. Potential medical or surgical risks:               <ul style="list-style-type: none"> <li>i. Death</li> <li>ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure</li> <li>iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction</li> <li>iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions</li> </ul> </li> <li>b. Potential psychosocial risks:               <ul style="list-style-type: none"> <li>i. Problems with body image</li> <li>ii. Post-surgery depression or anxiety</li> <li>iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies</li> <li>iv. Changes to the living donor's lifestyle from donation</li> </ul> </li> <li>c. Potential financial impacts:               <ul style="list-style-type: none"> <li>i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs</li> <li>ii. Need for life-long follow up at the living donor's expense</li> <li>iii. Loss of employment or income</li> <li>iv. Negative impact on the ability to obtain future employment</li> <li>v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance</li> <li>vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance</li> </ul> </li> </ul>



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**Table 14-2: Additional Requirements for the Informed Consent of Living Kidney Donors**

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
<b>Provide to all living kidney donors</b>	<p>Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:</p> <ol style="list-style-type: none"> <li>On average, living donors will have a 25-35% permanent loss of kidney function after donation.</li> <li>Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.</li> <li>Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD.</li> <li>Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.</li> <li>Dialysis is required if the living donor develops ESRD.</li> <li>Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to <i>Policy 8.3: Kidney Allocation Points</i>.</li> </ol>
<b>Disclose to all living kidney donors</b>	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>Decreased kidney function</li> <li>Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period</li> </ul>
<b>Disclose to all female living kidney donors</b>	<p>Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation</p>

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**Table 14-3: Additional Requirements for the Informed Consent of Living Liver Donors**

The recovery hospital must:	These additional elements as components of informed consent for living liver donors:
<b>Disclose to all living liver donors</b>	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>Acute liver failure with need for liver transplant-</li> <li>Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation-</li> <li>Risk of red cell transfusions or other blood products-</li> <li>Biliary complications, including leak or stricture that may require additional intervention-</li> <li>Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks-</li> </ul>

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**Table 14-4: Additional Requirements for the Informed Consent of Living VCA Donors**

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:
<p><b><u>Disclose to all living non-genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions</u></b></p>	<p><u>There are surgical, psychosocial, and financial risks associated with living non-genitourinary VCA donation, 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"> <li>• <u>Potential surgical risks:</u> <ul style="list-style-type: none"> <li>• <u>Loss of function</u></li> <li>• <u>Physical disability</u></li> <li>• <u>Physical disfigurement</u></li> </ul> </li> <li>• <u>Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome</u></li> <li>• <u>Potential financial impacts: Procedure may not be covered by health insurance</u></li> </ul>
<p><b><u>Disclose to all living genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions</u></b></p>	<p><u>There are surgical, psychosocial, and financial risks associated with living genitourinary VCA donation, 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"> <li>• <u>Potential surgical risks:</u> <ul style="list-style-type: none"> <li>• <u>Bowel injury</u></li> <li>• <u>Decreased fertility (male)</u></li> <li>• <u>Inability to bear children (female)</u></li> <li>• <u>Loss of function</u></li> <li>• <u>Need for hormonal replacement therapy</u></li> <li>• <u>Pain or discomfort with intercourse</u></li> <li>• <u>Physical disfigurement (male)</u></li> <li>• <u>Urinary tract injury or dysfunction</u></li> </ul> </li> <li>• <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></li> <li>• <u>Potential financial impacts: Procedure may not be covered by health insurance</u></li> </ul>

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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 14-5*.

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**Table 14-5: Required Recipient Outcome and Transplanted Organ Survival Data  
(The requirements in Table 14-5 do not apply to VCA donations)**

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"> <li>• National 1-year patient and transplanted organ survival</li> <li>• The hospital’s 1-year patient and transplanted organ survival</li> <li>• Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital</li> </ul>
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"> <li>• National 1-year patient and transplanted organ survival</li> <li>• The recipient hospital’s 1-year patient and transplanted organ survival</li> <li>• Notification about all CMS outcome requirements not being met by the recipient hospital</li> </ul>
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"> <li>• National 1-year patient and transplanted organ survival</li> </ul>

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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 14-6* through *14-10* below.

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**Table 14-6: Requirements for Living Donor Medical Evaluations**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>General donor history</b>	<ol style="list-style-type: none"> <li>1. A personal history of significant medical conditions which include but are not limited to:               <ol style="list-style-type: none"> <li>a. Hypertension</li> <li>b. Diabetes</li> <li>c. Lung disease</li> <li>d. Heart disease</li> <li>e. Gastrointestinal disease</li> <li>f. Autoimmune disease</li> <li>g. Neurologic disease</li> <li>h. Genitourinary disease</li> <li>i. Hematologic disorders</li> <li>j. Bleeding or clotting disorders</li> <li>k. History of cancer including melanoma</li> </ol> </li> <li>2. History of infections</li> <li>3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication.</li> <li>4. Allergies</li> <li>5. An evaluation for coronary artery disease</li> </ol>
<b>General family history</b>	<ul style="list-style-type: none"> <li>• Coronary artery disease</li> <li>• Cancer</li> </ul>
<b>Social history</b>	<ul style="list-style-type: none"> <li>• Occupation</li> <li>• Employment status</li> <li>• Health insurance status</li> <li>• Living arrangements</li> <li>• Social support</li> <li>• Smoking, alcohol and drug use and abuse</li> <li>• Psychiatric illness, depression, suicide attempts</li> <li>• Increased risk behavior as defined by the <i>U.S. Public Health Services (PHS) Guideline</i></li> </ul>
<b>Physical Exam</b>	<ul style="list-style-type: none"> <li>• Height</li> <li>• Weight</li> <li>• BMI</li> <li>• Vital signs</li> <li>• Examination of all major organ systems</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<p><b>General laboratory and imaging tests</b></p>	<ul style="list-style-type: none"> <li>• Complete blood count (CBC) with platelet count</li> <li>• Blood type and subtype as specified in <i>Policy 14.5: Living Donor Blood Type Determination and Reporting</i> and its subsections</li> <li>• Prothrombin Time (PT) or International Normalized Ratio (INR)</li> <li>• Partial Thromboplastin Time (PTT)</li> <li>• Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)</li> <li>• HCG quantitative pregnancy test for premenopausal women without surgical sterilization</li> <li>• Chest X-Ray</li> <li>• Electrocardiogram (ECG)</li> </ul>
<p><b>Transmissible disease screening</b></p>	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> <li>1. CMV (Cytomegalovirus) antibody</li> <li>2. EBV (Epstein Barr Virus) antibody</li> <li>3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery</li> <li>4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery</li> <li>5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery</li> <li>6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery</li> <li>7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</li> <li>8. Syphilis testing</li> </ol> <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the <i>U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the <i>U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> <li>• Intradermal PPD</li> <li>• Interferon Gamma Release Assay (IGRA)</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Endemic transmissible diseases</b>	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.
<b>Cancer screening</b>	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: <ul style="list-style-type: none"> <li>• Cervical cancer</li> <li>• Breast cancer</li> <li>• Prostate cancer</li> <li>• Colon cancer</li> <li>• Lung cancer</li> </ul>

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### 14.4.B Additional Requirements for the Medical Evaluation of Living Kidney Donors

**Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Kidney-specific donor history</b>	A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: <ol style="list-style-type: none"> <li>a. Genetic renal diseases</li> <li>b. Kidney disease, proteinuria, hematuria</li> <li>c. Kidney injury</li> <li>d. Diabetes including gestational diabetes</li> <li>e. Nephrolithiasis</li> <li>f. Recurrent urinary tract infections</li> </ol>
<b>Kidney-specific family history</b>	<ul style="list-style-type: none"> <li>• Kidney disease</li> <li>• Diabetes</li> <li>• Hypertension</li> <li>• Kidney Cancer</li> </ul>
<b>Physical Exam</b>	<ul style="list-style-type: none"> <li>• Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring</li> </ul>
<b>Other metabolic testing</b>	<ul style="list-style-type: none"> <li>• Fasting blood glucose</li> <li>• Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)</li> <li>• Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Kidney-specific tests</b>	<ul style="list-style-type: none"> <li>• Urinalysis or urine microscopy</li> <li>• Urine culture if clinically indicated</li> <li>• Measurement of urinary protein and albumin excretion</li> <li>• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection</li> <li>• Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history</li> <li>• Patients with a history of nephrolithiasis or nephrolithiasis (&gt;3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:               <ul style="list-style-type: none"> <li>○ Calcium</li> <li>○ Oxalate</li> <li>○ Uric acid</li> <li>○ Citric acid</li> <li>○ Creatinine</li> <li>○ Sodium</li> </ul> </li> </ul>
<b>Anatomic assessment</b>	Determine: <ul style="list-style-type: none"> <li>• Whether the kidneys are of equal size</li> <li>• If the kidneys have masses, cysts, or stones</li> <li>• If the kidneys have other anatomical defects</li> <li>• Which kidney is more anatomically suited for transplant</li> </ul>

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### 14.4.C Additional Requirements for the Medical Evaluation of Living Liver Donors

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**Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Liver-specific family history</b>	<ul style="list-style-type: none"> <li>• Liver diseases</li> <li>• Bleeding or clotting disorders</li> </ul>
<b>General laboratory and imaging tests</b>	<ul style="list-style-type: none"> <li>• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Liver-specific tests</b>	<ul style="list-style-type: none"> <li>• Hepatic function panel</li> <li>• Ceruloplasmin in a donor with a family history of Wilson’s Disease</li> <li>• Iron, iron binding capacity, ferritin</li> <li>• Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype</li> <li>• must develop and follow a written protocol for testing for genetic diseases</li> <li>• Hospitals must develop and follow a written protocol for screening for autoimmune disease</li> <li>• Hospitals must develop and follow a written protocol for pre-donation liver biopsy</li> </ul>
<b>Anatomic assessment</b>	<p>A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor.</p> <p>The evaluation must include at least all of the following:</p> <ul style="list-style-type: none"> <li>• Assessment of projected graft volume</li> <li>• Donor’s remnant volume,</li> <li>• Vascular anatomy</li> <li>• Presence of steatosis</li> </ul>

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**14.4.D Additional Requirements for the Medical Evaluation of Living VCA Donors**

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**Table 14-9: Additional Requirements for the Medical Evaluation of Living VCA Donors**

<u>This evaluation must be completed:</u>	<u>Including evaluation for and assessment of this information:</u>
<b><u>Transmissible disease screening for all VCA donors</u></b>	<p><u>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:</u></p> <ul style="list-style-type: none"> <li>• <u>Toxoplasma Immunoglobulin G (IgG) antibody test</u></li> </ul>
<b><u>Additional Specific medical history for uterus donors</u></b>	<ul style="list-style-type: none"> <li>• <u>Gynecological and obstetric history including prior childbirth</u></li> </ul>
<b><u>Additional Specific tests for uterus donors</u></b>	<ul style="list-style-type: none"> <li>• <u>Pap smear</u></li> </ul>
<b><u>Additional anatomic assessment for uterus donors</u></b>	<ul style="list-style-type: none"> <li>• <u>Pelvic exam</u></li> <li>• <u>A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation</u></li> </ul>



This evaluation must be completed:	Including evaluation for and assessment of this information:
<p><b><u>Additional transmissible disease screening for uterus donors</u></b></p>	<p><u>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:</u></p> <ul style="list-style-type: none"> <li>• <u>Bacterial Vaginosis (Gardnerella Vaginalis)</u></li> <li>• <u>Chlamydia by nucleic acid test (NAT)</u></li> <li>• <u>Gonorrhea by nucleic acid test (NAT)</u></li> <li>• <u>Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test</u></li> <li>• <u>Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA</u></li> <li>• <u>Trichomoniasis</u></li> <li>• <u>Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)</u></li> </ul>

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### 14.4.E Living Donor Exclusion Criteria

**Table 14-10: Living Donor Exclusion Criteria**

Exclusion Criteria	
<p><b>Exclusion criteria for all Living Donors</b></p>	<p>Living donor recovery hospitals may exclude a donor with any condition that, in the hospital’s medical judgment, causes the donor to be unsuitable for organ donation.</p> <p>Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</p> <ul style="list-style-type: none"> <li>• Is both less than 18 years old and mentally incapable of making an informed decision</li> <li>• HIV, unless the requirements for a variance are met, according to <i>Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors</i></li> <li>• Active malignancy, or incompletely treated malignancy</li> <li>• High suspicion of donor coercion</li> <li>• High suspicion of illegal financial exchange between donor and recipient</li> <li>• Evidence of acute symptomatic infection (until resolved)</li> <li>• Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality</li> </ul>
<p><b>Additional Exclusion Criteria for Living Kidney Donors</b></p>	<p>Kidney recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> <li>• Uncontrollable hypertension or history of hypertension with evidence of end organ damage</li> <li>• Diabetes</li> </ul>

Exclusion Criteria	
<p><b>Additional Exclusion Criteria for Living Liver Donors</b></p>	<p>Liver recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> <li>• HCV RNA positive</li> <li>• HBsAg positive</li> <li>• Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes</li> <li>• Expected donor remnant volume less than 30% of native liver volume</li> <li>• Prior living liver donor</li> </ul>

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## 130 **14.5 Living Donor Blood Type Determination and Reporting**

131 Recovery hospitals must develop and comply with a written protocol for blood type determination and  
 132 reporting that includes all of the requirements below.

133

### 134 **14.5.A Living Donor Blood Type Determination**

135 The recovery hospital must ensure that each living donor’s blood type is determined by testing  
 136 at least two donor blood samples prior to generation of the living donor ID. The recovery  
 137 hospital must develop and comply with a written protocol to resolve conflicting primary blood  
 138 type results.

139

140 Living donor blood samples must:

141

- 142 1. Be drawn on two separate occasions
- 143 2. Have different collection times
- 144 3. Be submitted as separate samples
- 145 4. Have results indicating the same blood type

146

147 The recovery hospital must document that blood type determination was conducted according  
 148 to the hospital’s protocol and the above requirements.

149

### 150 **14.5.B Living Donor Blood Subtype Determination**

151 Subtyping is optional for living donors.

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153 If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion samples are  
 154 available, then subtyping must be completed according to *Table 14-11*.

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**Table 14-11: Subtyping Requirements by First Subtype Result**

If the donor's primary blood type is:	A second subtyping must be completed if the first subtype result is:
A	Blood type A, non-A <sub>1</sub>
AB	Blood type AB, non-A <sub>1</sub> B

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Living donor blood samples for subtyping must:

1. Be tested using pre-red blood cell transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

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All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and living donor transplant compatibility or allocation must be based on the primary blood type.

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If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

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### **14.5.C Reporting of Living Donor Blood Type and Subtype**

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The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN Contractor using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN Contractor for blood type. For VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
  - a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
  - b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results
  - c. Match the result reported to the OPTN Contractor or VCA donor medical record

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The recovery hospital must document that reporting was completed according to the hospital's protocol and the above requirements.

177 **14.6 Placement of Living Donor Organs**

178 **14.6.A Prospective Crossmatching prior to Kidney Placement**

179 A prospective crossmatch is mandatory for all potential kidney living donor recipients.  
 180 Guidelines for policy development, including assigning risk and timing of crossmatch testing, are  
 181 outlined in *Policy 4: Histocompatibility*.  
 182

183 **14.6.B Placement of Non-directed Living Donor Organs**

184 Prior to determining the placement of a non-directed living donor organ, including non-directed  
 185 organs from domino donors and non-domino therapeutic organ donors, the recovery hospital  
 186 must obtain the match run of its waiting list candidates from its local OPO or the Organ Center.  
 187 When a non-directed living donor organ is placed, the recovery hospital must document how the  
 188 organ is placed and the rationale for placement.  
 189

190 This requirement does not apply to non-directed living kidney donors who donate a kidney  
 191 through a Kidney Paired Donation (KPD) arrangement.  
 192

193 **14.6.C Transplant Hospital Acceptance of Living Donor Organs**

194 A transplant hospital must only accept and transplant living donor organs according to *Table 14-*  
 195 *12* below.  
 196

197 **Table 14-12: Transplant Hospital Requirements for Accepting and Transplanting**  
 198 **Living Donor Organs**

If this type of living donor organ is being recovered:	Then the recovery hospital must:
Kidney	Meet the requirements according to the <i>OPTN Bylaws E.6: Kidney Transplant Programs that Perform Living Donor Recovery</i>
Liver	Meet the requirements according to the <i>OPTN Bylaws F.8: Liver Transplant Programs that Perform Living Donor Recovery</i>
Other organ types, excluding kidney or liver	Have current designated transplant program approval for that organ type

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 200 **14.7 Living Donor Pre-Recovery Verification**

201 Recovery hospitals must develop and comply with a written protocol to perform pre-recovery  
 202 verifications as required below.  
 203

204 The recovery hospital must conduct a pre-recovery verification that meets *all* of the following  
 205 requirements:  
 206

- 207 1. The verification must occur prior to the induction of general anesthesia on the day of the living  
 208 donor recovery.

209 2. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery  
 210 verification to verify all of the following information according to *Table 14-13* below. Recovery  
 211 hospitals may use the OPTN organ tracking system for assistance in completing these verifications.  
 212

213 **Table 14-13: Pre-Recovery Verification Requirements**

The recovery hospital must verify <i>all</i> of the following information:	Using at least <i>one</i> of the following:	By <i>both</i> of the following individuals:
Donor ID	<ul style="list-style-type: none"> <li>• Donor identification band containing the donor ID</li> <li>• Donor identification band and OPTN computer system</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Organ type and laterality (if applicable)	<ul style="list-style-type: none"> <li>• OPTN computer system</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	<ul style="list-style-type: none"> <li>• Donor blood type and subtype source documents</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Intended recipient unique identifier	<ul style="list-style-type: none"> <li>• Recipient medical record</li> <li>• OPTN computer system</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Intended recipient blood type	<ul style="list-style-type: none"> <li>• Recipient medical record</li> <li>• OPTN computer system</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> <li>• OPTN computer system</li> <li>• Recipient medical record</li> <li>• Attestation following verification of donor and recipient blood types</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>
Correct donor organ has been identified for the correct intended recipient	<ul style="list-style-type: none"> <li>• Donor medical record</li> <li>• OPTN computer system</li> <li>• Attestation following verification of donor ID, organ, and recipient unique identifier</li> </ul>	<ol style="list-style-type: none"> <li>1. Recovery surgeon</li> <li>2. Licensed health care professional</li> </ol>

214 The recovery hospital must document that the verification was completed according to the hospital's  
 215 protocol and the above requirements.  
 216

## 217 **14.8 Packaging, Labeling, and Transporting of Living Donor Organs,** 218 **Extra Vessels, and Tissue Typing Materials**

219 Recovery hospitals are responsible for packaging and labeling any living donor organs, or tissue typing  
 220 specimens that are recovered from living donors according to *Policy 16: Organ and Extra Vessels*  
 221 *Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:  
 222  
 223

- 224 • Living donor organs or tissue typing specimens are recovered and must be transported outside the
- 225 recovery hospital
- 226 • A living donor organ or tissue typing specimens require repackaging by a transplant hospital for
- 227 transport outside the transplant hospital

228  
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#### 14.8.A Living Donor Extra Vessels Recovery and Storage

230 A recovery hospital must only recover extra vessels for transplant if the living donor consents  
231 to the removal of extra vessels for transplant. The extra vessels from a living donor must only  
232 be used for the implantation or modification of a solid organ transplant for the original intended  
233 recipient.

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Any extra vessels recovered from living donors must be stored according to *Policy 16.6.B: Extra Vessels Storage*.

### 14.9 Requirements for Domino Donors and Non-Domino Therapeutic Donors

240 Although domino donors and non-domino therapeutic donors are considered living donors, the  
241 requirements in *Policy 14: Living Donation* are limited only to *Policies 14.9.A* through *14.9.E* below for  
242 domino donors and non-domino therapeutic donors.

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#### 14.9.A Informed Consent Requirements for Domino Donors and Non-Domino Therapeutic Donors

246 Recovery hospitals must obtain the donor's signature on a document that confirms that the  
247 donor:

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1. Is willing to donate.
2. Is free from inducement and coercion.
3. Has been informed that the donor may decline to donate at any time.
4. Has received information on treatment options that would not involve organ donation.

254 Recovery hospitals must also provide *all* of the following to domino donors and non-domino  
255 therapeutic donors:

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1. The disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.
2. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations.
3. The disclosure that health information obtained during the evaluation for donation is subject to the same regulations as all health records and could reveal conditions that must be reported to local, state, or federal public health authorities.
4. The disclosure that any new information discovered during the domino donor's or non-domino therapeutic donor's first two years of post-donation care that indicates risk of

267 potential transmission of infectious disease or malignancy to the recipient of the domino  
268 donor's or non-domino therapeutic donor's native organ:

- 269 a. May need to be reported to local, state, or federal public health authorities  
270 b. Will be disclosed to the recipient's transplant hospital  
271 c. Will be reported through the OPTN Improving Patient Safety Portal

272

273 5. Information on treatment options that would not involve organ donation.

274 6. An opportunity to discontinue the donor consent or evaluation process in a way that is  
275 protected and confidential.

276

277 Documentation of the informed consent must be maintained in the donor medical record.

278

279 **14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-**  
280 **Domino Therapeutic Donors**

281 Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according  
282 to *all* of the following requirements:

283

284 1. Perform an evaluation for the presence of behaviors that may increase risk for disease  
285 transmission as defined by the *U.S. Public Health Service (PHS) Guideline*.

286 2. Screen the domino donor or non-domino therapeutic donor for all of the following  
287 according to *Policy 14.4: Medical Evaluation Requirements for Living Donors, Table 14-6:*  
288 *Requirements for Living Donor Medical Evaluations*.

289 3. Transmissible diseases screening.

290 4. Endemic transmissible diseases.

291 5. Cancer screening.

292 6. Develop and comply with written protocols for the domino donor and non-domino  
293 therapeutic donor exclusion criteria considering incorporating as appropriate the elements  
294 of *Table 14-10: Living Donor Exclusion Criteria*.

295 7. Register and verify the blood type of the domino donor or non-domino therapeutic donor  
296 according to *Policy 14.5: Living Donor Blood Type Determination and Reporting*.

297

298 Documentation of the psychosocial and medical evaluation must be maintained in the donor  
299 medical record.

300

301 **14.9.C Recovery of Domino Donor and Non-Domino Therapeutic Donor Organs**

302 Transplant hospitals can recover domino donor and non-domino therapeutic donor organs if the  
303 hospital has current designated transplant program approval for that organ type.

304

305 **14.9.D Acceptance of Domino Donor and Non-Domino Therapeutic Donor Organs**

306 Transplant hospitals must only accept domino donor and non-domino therapeutic donor organs  
307 recovered at transplant hospitals that have a current designated transplant program approval  
308 for that organ type.

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