OPTN

Public Comment Proposal

Modify Data Collection on VCA Living Donors

OPTN Vascularized Composite Allograft Transplantation Committee

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Modify Data Collection on VCA Living Donors

Affected Policies:	*14.5: Living Donor Blood Type Determination and Reporting* *18.1: Data Submission Requirements* *18.2: Timely Collection of Data*
Sponsoring Committee:	*Vascularized Composite Allograft Transplantation*
Public Comment Period:	*August 4, 2020 – October 1, 2020*

Executive Summary

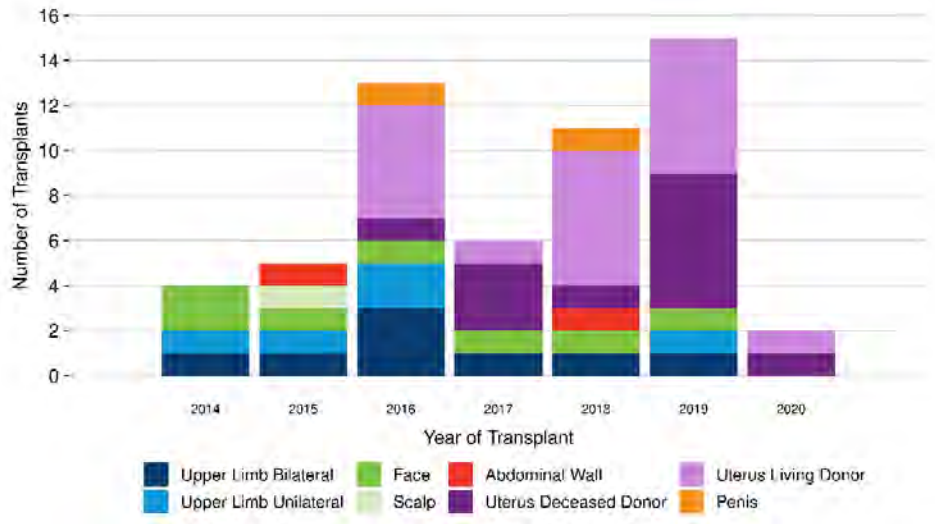
The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee proposes changes to data collection on living VCA donors. Living uterus donations were first performed in the U.S. in 2016 and have since increased in frequency. While the OPTN requires data collection on living donors of other organs, the OPTN does not require data collection on living VCA donors, though transplant programs voluntarily submit limited data on living VCA donors. This proposal would require submission of data collection instruments for living VCA donors, including the Living Donor Registration (LDR) and Living Donor Follow-up (LDF). This proposal would also add new data elements to the LDR and LDF specific to living VCA donors, particularly uterus. These new data collection requirements would improve the OPTN's ability to monitor patient safety. This proposal was developed in conjunction with a related public comment proposal, *Modify Living Donation Policy to Include Living VCA Donors*, which was also released this cycle.

The proposed data collection would be collected through UNet^{SM}. Currently, all VCA data is collected through a stand-alone system. The OPTN plans to program all VCA data collection into UNet, which is the system used for all other organs. Since the number of VCA transplants are increasing, it will ultimately be more efficient for the OPTN to program new VCA data collection requirements into UNet, rather than making significant changes within the existing stand-alone system for VCA. Programming any VCA data collection within UNet requires policy changes, as current policy contains exclusions for VCA based on the stand-alone data collection process. This proposal contains needed policy changes related to programming living donor VCA data collection into UNet. A separate proposal released for public comment this cycle, *Programming VCA Allocation in UNet,* contains needed policy changes for programming deceased donor VCA allocation and data collection in UNet.

Background

The first living donor uterus transplants in the U.S. were performed in 2016 and have since increased in frequency. As of June 2020, more than half of all uterus transplants performed in the U.S. were made possible through living donation (**Figure 1**). The OPTN is aware of nine children born to uterus recipients, and six of those children were born to individuals who received their uterus from a living donor.[1]

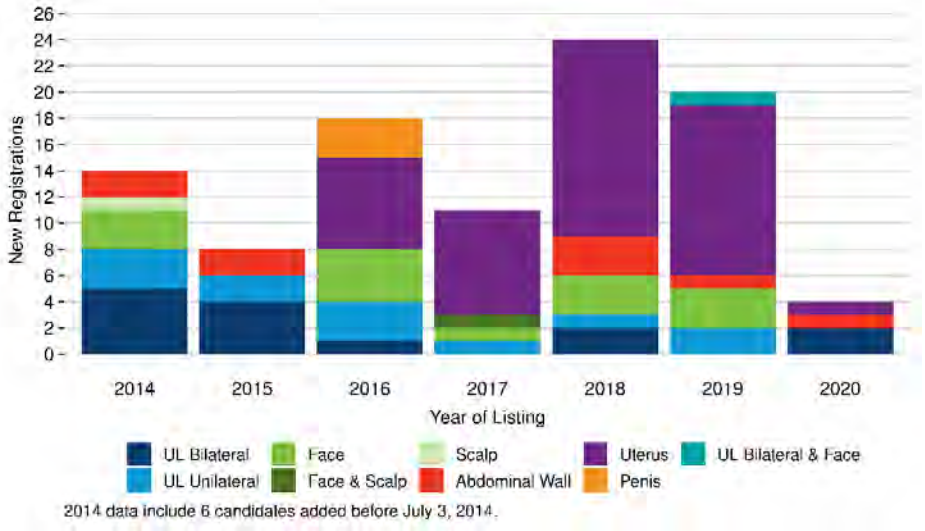
Figure 1: VCA Transplants in the U.S.: July 3, 2014 – June 3, 2020[2]



Over half of the candidates added to the vascularized composite allograft (VCA) waiting list since 2016 were uterus candidates, making uterus the most sought-after VCA transplant (**Figure 2**).

[1] Based on OPTN data as of June 29, 2020.
[2] Based on OPTN data as of June 3, 2020.

Figure 2: Additions to the VCA Waitlist in the U.S.: July 3, 2014 – June 3, 2020[3]



Living donation of other VCA types may become more common in the near future. For example, a living donor testicle transplant between twin brothers was performed in Serbia in 2019.[4] Other cases of living VCA donation have been reported in medical literature, sometimes using terms other than VCA or living donation.[5] These examples include living donation of sections of the abdominal wall, omentum, and other vascularized tissue flaps used for reconstructive surgeries in the recipients.[6]

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."[7] Similarly, one of the OPTN Data Collection Principles is to "ensure patient safety when no alternative sources of data exist."[8] In support of these goals, the OPTN collects data on living donors under the authority of the OPTN Final Rule.[9, 10] OPTN *Policy 18.1 Data Submission Requirements* and *Policy 18.2 Timely Collection of Data* outline requirements for data submission related to living donors. VCA is currently excluded from these policies, though transplant programs voluntarily report limited living VCA donor data to the OPTN. These data are not systematically collected elsewhere.

OPTN *Policy 14: Living Donation* outlines various requirements for living donation such as medical evaluations, but VCA is excluded from several sections of living donor policy. A separate but related proposal released for public comment this cycle, *Modify Living Donation Policy to Include Living VCA Donors*, proposes adding new requirements for informed consent and medical evaluations for living VCA donors. The proposal to modify living donation policy is complementary to this proposal, which contains

[3] Ibid.
[4] Denise Grady, "Surgeons Transplant a Testicle From One Brother to His Twin," *The New York Times*, December 6, 2019, https://www.nytimes.com/2019/12/06/health/testicles-transplant.html.
[5] Bohdan Pomahac et al., "Living Donation of Vascularized Composite Allografts," *Plastic and Reconstructive Surgery* 142, no. 3 (September 2018): 406e, https://doi.org/10.1097/PRS.0000000000004659
[6] Pomahac, "Living Donation of Vascularized Composite Allografts," 406e.
[7] "OPTN/UNOS Strategic Plan 2018-2021," OPTN, accessed June 25, 2020, https://optn.transplant.hrsa.gov/media/2392/executive_publiccomment_strategicplan_20180122.pdf
[8] "Principles of Data Collection," OPTN, accessed June 4, 2020, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[9] 42 CFR §121.11(b)(2).
[10] 42 CFR §121.11(a)(1)(ii).

associated data collection requirements that would enable the OPTN to monitor member compliance and thereby promote the safety of transplant recipients and living donors. These objectives align with the OPTN Data Collection Principles.[11]

Given the increase in living uterus donation and transplantation and the potential for living donation of other types of VCA, the OPTN VCA Transplantation Committee (Committee) proposes modifying living donor data collection requirements to include VCA. No required data collection currently exists for living VCA donation. Without requiring these data, the OPTN is less equipped to monitor living VCA donor and recipient safety, as transplant programs observing poor donor outcomes, or donor characteristics linked to poor recipient outcomes, may not report this information to the OPTN. Accordingly, this proposal aligns with the OPTN strategic plan goal and the OPTN Data Collection Principle to promote living donor and recipient safety.[12,13]

The OPTN manages allocation and data collection for all other organs via the OPTN computer system known as UNet[SM]. However, allocation and data collection for VCA are not currently programmed in UNet and are managed separately. This proposal contains policy changes required to program living VCA donor data collection in UNet. A separate but related proposal, *Programming VCA Allocation in UNet*, addresses needed policy changes for programming deceased donor VCA allocation and data collection in UNet.

Purpose

The purpose of this proposal is to improve the OPTN's ability to monitor patient safety by requiring data collection on living VCA donors, and by adding VCA-specific data elements to the data collection instruments currently used for living donors of other organs.

This proposal would require the submission of official OPTN data that are not presently collected by the OPTN. As these data are proposed to be collected under §121.11(b)(2) of the OPTN Final Rule, after OPTN Board approval they would be submitted for OMB approval under the Paperwork Reduction Act of 1995. Once OMB-approved, the data would be maintained according to the OPTN System of Records Notice.[14] This would require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Overview of Proposal

This proposal would require submission of data collection instruments for living VCA donors, including but not limited to data that is currently submitted to the OPTN voluntarily. This proposal includes new data elements specific to living donation of uterus and other VCA. These changes will promote living donor safety, aid in monitoring member compliance, and enable outcome assessment of living VCA donors. This proposal also includes policy changes needed to program living VCA donation data collection instruments within UNet.

[11] OPTN, "Principles of Data Collection."
[12] "Visions and Goals," OPTN, accessed June 4, 2020, https://optn.transplant.hrsa.gov/governance/about-the-optn/vision-goals/.
[13] OPTN, "Principles of Data Collection."
[14] "System of Record Notice 09-15-0055," Health Resources and Services Administration, accessed June 4, 2020, https://www.hrsa.gov/about/privacy-act/09-15-0055.html

Transplant programs currently submit data on living VCA donors to the OPTN on a voluntary basis via the VCA Living Donor Feedback form. This form includes basic donor information like ethnicity/race, gender, and blood type. In addition to the Living Donor Feedback form, the OPTN uses two other data collection instruments to collect more detailed information on living donors of other organs: Living Donor Registration (LDR) and Living Donor Follow-up (LDF). Transplant programs do not currently use the LDR or LDF for living VCA donors, but this proposal would require submission of the LDR and LDF for living VCA donors.

The LDR is submitted by the living donor's recovery hospital shortly after organ recovery and includes collection of donor demographic information; pre-donation clinical information; surgical information; post-operative information; post-operative complications; and other post-operative clinical information. The LDR has data elements relevant for all organs, which would apply to VCA following implementation of this proposal, as well as data elements specific to kidney, liver, and lung. The LDF is submitted by the living donor's recovery hospital around the six-month, one-year, and two-year anniversary of the donation date. The LDF collects donor status information, clinical information, and complications. The LDF also has data elements relevant for all organs, which would apply to VCA following implementation of this proposal, as well as data elements specific to kidney, liver, and lung. **Appendix 1: *Current LDR and LDF Data Collection Summary*** contains more details on the LDR and LDF.

Proposed VCA Data Elements: LDR

Most of the VCA data elements that the Committee proposes adding to the LDR are specific to uterus, but a small number of proposed data elements would apply to all living VCA donors or to donors of VCA other than uterus. These proposed data elements are summarized in **Table 1** and **Table 2**. Other data currently collected on the LDR for all other living donors, as outlined in **Appendix 1**, would also be collected for all VCA living donors.

Table 1: Proposed Data Elements to Add to LDR – Living Donor Uterus

Section of LDR	Data Elements
Pre-Donation Uterus Clinical Information	Human Papillomavirus (HPV) - cervical specimen only by DNA or mRNA
	Herpes Simplex Virus (HSV) 1/2 (IgG)
	Gonorrhea (NAT)
	Chlamydia (NAT)
	Vaginal Candidiasis (collected at the time of evaluation)
	Vaginal Candidiasis (collected at the time of donation)
	Bacterial Vaginosis *(Gardnerella vaginalis)*
	Trichomoniasis
	Other Testing
	Uterine Imaging
	Gravidity
	Parity
	Spontaneous Abortion
	Induced Abortion
	Prior Full Term Live Births
Uterus Surgical Information	Intended Procedure Type
	Conversion from Robotic to Open
	Operative Time (surgical time from skin to skin)
	Ovaries Removed
	Intra-Operative Complications
	Ureter Injury
	Anesthetic Complications
	Other Complications
Uterus Post-Operative Information	Length of ICU Stay (days)
Uterus Related Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Complications Requiring Intervention

Table 2: Proposed Data Elements to Add to LDR – Other or All Living Donor VCA[15]

Section of LDR	Data Elements
Pre-Donation All VCA Clinical Information	Toxoplasma IgG
Other VCA Surgical Information	Intra-Operative Complications
Other VCA Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Complications Requiring Intervention
All VCA Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Reoperation
	Any Readmission After Initial Discharge

Pre-Donation Clinical Information

Uterus transplants enable individuals with uterine factor infertility to carry their own pregnancy.[16, 17, 18] Accordingly, the Committee proposes adding several data elements to the pre-donation section of the LDR related to the function of the uterus in pregnancy and potential impact on the development of a fetus within the transplanted uterus. These data elements fall into three primary categories: infectious disease testing, uterine imaging, and medical history related to pregnancy and childbirth.

Infectious Disease Testing

The infectious disease testing data elements include human papillomavirus (HPV), herpes simplex virus (HSV), gonorrhea, chlamydia, vaginal candidiasis (collected at the time of medical evaluation and at the time of donation), bacterial vaginosis *(Gardnerella vaginalis)*, and trichomoniasis. The Committee believes it is important to collect these data because infection of the donated uterus could impact the health of the recipient and the outcome of a uterus transplant. Furthermore, active infections of bacterial vaginosis and trichomoniasis in pregnant women have been associated with adverse pregnancy outcomes like fetal demise, premature delivery, and low birth weight.[19,20] In the proposal to update Living Donor OPTN policies, all of these tests would be required as part of required evaluations of potential living uterus donors. Collecting testing results by the OPTN would aid in ensuring member compliance as well as protecting patient safety and providing data for outcome assessment.

Based on recommendations from the OPTN Disease Transmission Advisory Committee (DTAC), the Committee proposes collecting data on toxoplasma testing for all living VCA donors (not just uterus). Testing for toxoplasma is important for uterus transplant due to the potential for reactivation under immunosuppression and infection of a fetus. Fetal infection (congenital toxoplasmosis) can have lifelong implications including severe eye infections and mental disability.[21] These data would also be collected

[15] "Other VCA" refers to VCA other than uterus. "All VCA" includes uterus.
[16] "A North American First: Live Birth from Deceased-Donor Uterine Transplant at Cleveland Clinic," Cleveland Clinic, accessed June 5, 2020, https://consultqd.clevelandclinic.org/a-north-american-first-live-birth-from-deceased-donor-uterine-transplant-at-cleveland-clinic/.
[17] "Penn Uterus Transplant Program," Penn Medicine, accessed June 5, 2020, https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/penn-fertility-care/uterus-transplant.
[18] "First in the United States: Two Babies Born to Mothers Who Received Transplanted Uteri," Baylor Scott & White Health, accessed June 5, 2020, https://www.bswhealth.med/Pages/departments/transplant/uterus-transplantation.aspx.
[19] Maria Romoren et al., "Trichomoniasis and bacterial vaginosis in pregnancy: inadequately managed with the syndromic approach," *Bulletin of the World Health Organization* 85, no. 4 (2007): 245-324, https://www.who.int/bulletin/volumes/85/4/06-031922/en/.
[20] Elizabeth M. McClure and Robert L. Goldenberg, "Infection and stillbirth," *Seminars in Fetal and Neonatal Medicine* 14, no. 4 (2009): 182-189, doi: 10.1016/j.siny.2009.02.003.
[21] "Toxoplasmosis," Mayo Clinic, accessed May 28, 2020, https://www.mayoclinic.org/diseases-conditions/toxoplasmosis/symptoms-causes/syc-20356249.

for living donors of other VCA types because once a person is infected with *Toxoplasma gondii*, tachyzoites have a propensity for skeletal muscle.[22] While living VCA donations involving skeletal muscle have not yet been reported to the OPTN, living donation of muscular VCA, including abdominal wall, may be performed in the future.[23]

Uterine Imaging

In addition to infectious disease testing, the Committee proposes collecting data on uterine imaging on the pre-donation section of the LDR specific to uterus. As with the infectious disease testing, the proposed additions to living donor OPTN policies would require "a radiological assessment… to determine if the uterus is anatomically suitable for transplantation." The corresponding data element on the LDR for uterine imaging would provide transplant programs with the opportunity to document any abnormal findings. While the Committee recognizes that programs are unlikely to accept a uterus with abnormalities at this time, the Committee believes it is important to provide transplant programs with the opportunity to document findings at their discretion, particularly given that uterine transplantation remains a novel and developing field.

Medical History

The Committee proposes collecting detailed data related to the living donor's medical history of pregnancy and childbirth, since pregnancy and childbirth are the desired outcomes of uterus transplant. The Committee proposes collecting data on gravidity and parity[24] as well as prior full live term births (described in more detail below) to capture a comprehensive overview of the donor's pregnancy and birth history. The Committee also believes it is important to collect these data in part because there is not consensus in the community as to whether nulliparous[25] donors should be accepted. Previous successful pregnancy is a positive indicator of uterine function, whereas no history of pregnancy leaves open the possibility of infertility, which can be caused by a uterine condition like endometriosis.[26] Accordingly, the Committee believes it is important for the OPTN to monitor if transplant programs begin accepting nulliparous donors in order to assess the outcomes of the transplant recipients.

The Committee proposes collecting data on a donor's history of spontaneous abortion (miscarriage) as a history of miscarriage may be indicative of a uterine condition.[27] Though the risk of uterine damage due to induced abortion is low,[28] the Committee also proposes collecting data on a donor's history of induced abortion because some transplant programs have not been willing to accept living uterus donors with a significant history of instrumentation of the endometrial cavity. As there is some evidence that individuals with a history of miscarriage or induced abortions are at increased risk for adverse

[22] J.G. Montoya and Oliver Liesenfeld, "Toxoplasmosis," *Lancet* 363 (2004): 1965.
[23] Pomahac, "Living Donation of Vascularized Composite Allografts," 408e.
[24] Gravidity is the number of times a patient has been pregnant, regardless of pregnancy outcome. Parity is the number of pregnancies reaching 20 weeks and 0 days of gestation or beyond, regardless of the number of fetuses or outcomes. Source: "reVITALize: Obstetrics Data Definitions," The American College of Obstetricians and Gynecologists, accessed June 26, 2020, https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions
[25] Nulliparous refers to having a parity of zero, so a nulliparous donor would refer to a uterus donor who has had zero pregnancies reaching 20 weeks and 0 days or gestation or beyond. Source: The American College of Obstetricians and Gynecologists, ""reVITALize: Obstetrics Data Definitions."
[26] "Infertility," Mayo Clinic, accessed June 4, 2020, https://www.mayoclinic.org/diseases-conditions/infertility/symptoms-causes/syc-20354317.
[27] "Uterine Conditions," March of Dimes, accessed June 4, 2020, https://www.marchofdimes.org/complications/uterine-conditions.aspx.
[28] "Induced Abortion," The American College of Obstetricians and Gynecologists, accessed June 4, 2020, https://www.acog.org/patient-resources/faqs/special-procedures/induced-abortion.

pregnancy outcomes,[29] it is important for the OPTN to collect these data to monitor recipient outcomes if transplant programs accept donors with this medical history.

Finally, the Committee proposes collecting data on prior full term live births and the type of delivery for each birth (vaginal or cesarean section). A history of prior full term live births is an indicator of the functionality of a potential donor uterus. However, cesarean sections (C-sections) can increase the risk of uterine rupture or other complications in subsequent pregnancies.[30] Additionally, one study noted that prior C-sections can make donor hysterectomy more difficult and may lead to longer operative times, higher blood loss, and increased risk of injury to the vessels that must be preserved for implantation.[31]

The Committee believes that collecting these data related to previous pregnancies and childbirth will not add significant administrative burden for transplant programs as this information will be collected as part of routine documentation of medical history.

Surgical Information

The Committee proposes collecting surgical information for uterus donors similar to the surgical information collected on the LDR for kidney and lung donors, including intended procedure type, conversion from robotic to open, intraoperative complications, and anesthetic complications. The Committee also proposes collecting data on operative time as it may vary by procedure type, and longer operative times may increase the risk of complications.[32] Whereas a typical hysterectomy takes one to three hours, a living uterus donation surgery can take eleven to thirteen hours.[33] The Committee also proposes collecting data on whether the donor's ovaries were removed during surgery. The Committee does not recommend removing ovaries as part of a living uterus donation, but at least one trial of living uterus donation performed outside of the U.S. included ovary removal for two donors.[34,35] Accordingly, the Committee believes it is important to document if ovaries are removed because ovary removal can have a significant impact on the donor's health, potentially causing early menopause and impacting cardiovascular morbidity.[36] The Committee also proposes adding a data element to collect information on intraoperative complications for VCA other than uterus.

Post-Operative Information and Complications

For uterus post-operative information, the Committee proposes adding a data element on length of stay in the intensive care unit (ICU) as a measure of living donor patient safety[37] and to be able to assess and convey the risks of living uterus donation to potential donors. The Committee also proposes collecting data on complications requiring intervention for uterus and for other VCAs following living donation. For

[29] Michael Makhlouf, "Adverse pregnancy outcomes among women with prior spontaneous or induced abortions," *American Journal of Obstetrics and Gynecology* 204, no. 1 (2011): S204-S205.
[30] "C-section," Mayo Clinic, accessed June 4, 2020, https://www.mayoclinic.org/tests-procedures/c-section/about/pac-20393655.
[31] Ramani et al., "DUETS (Dallas UtErus Transplant Study)," 2.
[32] Hang Cheng et al., "Prolonged operative duration is associated with complications: a systematic review and meta-analysis," *Journal of Surgical Research* 229 (September 2018): 134.
[33] Bridget M. Kuehn, "US Uterus Transplant Trials Under Way," *JAMA* 317, no. 10 (2017): 1005-1007.
[34] Ramani et al., "DUETS (Dallas UtErus Transplant Study)," 2.
[35] Roman Chmel et al, "Revaluation and lessons learned from the first 9 cases of a Czech uterus transplantation trial: four deceased donor and 5 living donor uterus transplantations," *American Journal of Transplantation* 19 (2019): 859.
[36] Melissa Wellons et al., "Early Menopause Predicts Future Coronary Heart Disease and Stroke: The Multi-Ethnic Study of Atherosclerosis," *Menopause: The Journal of the North American Menopause Society* 19, no. 10 (2012): 1081.
[37] Guy Haller et al., "Validity of Unplanned Admission to an Intensive Care Unit as a Measure of Patient Safety in Surgical Patients," *Anesthesiology* 103 (December 2005): 1121.

all living VCA donors, the Committee proposes collecting data on reoperations. These data are currently collected for living donors of kidney and liver. The Committee also proposes collecting data on any readmissions after initial discharge, which are currently collected for living donors of kidney, liver, and lung.

More details on proposed data elements along with supporting rationale for each VCA type and data collection instrument are located in **Appendix 2: *Proposed Modifications to VCA LDR and LDF Data Collection***. Definitions for each data element are located in **Appendix 3: *Proposed Data Definitions***.

Proposed VCA Data Elements: LDF

Most of the data elements that the Committee proposes adding to the LDF are specific to uterus, but the Committee also proposes adding one data element for living donor VCAs other than uterus. These proposed data elements are summarized in **Table 3**. Other data currently collected on the LDF for all living donors, as outlined in **Appendix 1**, would also be collected for all VCA living donors.

Table 3: Proposed Data Elements to Add to the LDF

Section of LDF	Data Elements
Complications	Complications Since Uterus Donation
	Menopausal Symptoms (uterus donors only)
	New Onset Psychological Symptoms (uterus donors only)
	Complications Since Other VCA Donation

On the LDF, the Committee proposes collecting information on complications since uterus donation, including menopausal symptoms and new onset psychological symptoms, as well as complications since other VCA donation. The Committee believes it is important to collect data on complications following living VCA donation – including uterus and other VCA – because living VCA donation is novel and there is not yet substantial literature on issues that may arise. For living uterus donors, the Committee believes it is important for the OPTN to monitor whether these donors experience menopause after donation. At least one trial of living uterus donation performed outside of the U.S. documented menopausal symptoms following ovary removal.[38,39] The Committee recognizes that this is not a desirable outcome for the donor since causing menopause has major implications for overall health and cardiovascular morbidity over time.[40] Finally, the Committee proposes collecting data on new onset psychological symptoms. A uterus transplantation trial using live donors in Sweden did not identify large increases in psychosocial symptoms within one year of transplant.[41] However, several studies have documented psychosocial complications following living donation of other organs,[42, 43, 44, 45] and the Committee

[38] Ramani et al., "DUETS (Dallas UtErus Transplant Study)," 2.
[39] Roman Chmel et al, "Revaluation and lessons learned from the first 9 cases of a Czech uterus transplantation trial: four deceased donor and 5 living donor uterus transplantations," *American Journal of Transplantation* 19 (2019): 859.
[40] Wellons, "Early Menopause Predicts Future Coronary Heart Disease and Stroke:,"1081.
[41] Niclas Kvarnström et al., "Live Donors of the Initial Observational Study of Uterus Transplantation—Psychological and Medical Follow-Up Until 1 Year After Surgery in the 9 Cases," *Transplantation* 101, no. 3 (March 2017): 669.
[42] Deborah Ummel, Marie Achille, and Jessina Mekkelholt, "Donors and recipients of living kidney donation: a qualitative metasummary of their experiences," *Journal of Transplantation*, 2011 (2011): 8.
[43] K.K. Clemens et al., "Psychosocial health of living kidney donors: a systematic review," *American Journal of Transplantation* 6 (2006): 2965.
[44] Sheila G. Jowsey and Terry D. Scheekloth, "Psychosocial factors in living organ donation: clinical and ethical challenges," *Transplantation Reviews* 22 (2008): 193.
[45] Neehar D. Parikh, Daniela Ladner, Michael Abecassis, and Zeeshan Butt, "Quality of life for donors after living donor liver transplantation: a review of the literature," *Liver Transplantation* 16 (2010): 1354-1355.

believes it is important to collect these data from living uterus donors. The Committee would appreciate feedback on whether data on new onset psychological symptoms should be collected for all VCA living donors and not just living uterus donors. Further consideration of the potential psychosocial impacts of living VCA donation is included in the proposal entitled *Modify Living Donation Policy to Include Living VCA Donors.* The purpose of collecting this information is to allow the OPTN to monitor for trends and to be able to inform prospective living uterus donors of the potential risks.

More details on the proposed data elements along with supporting rationale for each VCA type and data collection instrument are located in **Appendix 2**. Definitions for each data element are located in **Appendix 3**.

Proposed Policy Changes to Support Living Donor VCA in UNet

The proposed data collection would be collected through UNet. Currently, all VCA data is collected through a stand-alone system. The OPTN plans to program all VCA data collection into UNet, which is the system used for all other organs. Since the number of VCA transplants are increasing, it will ultimately be more efficient for the OPTN to program new VCA data collection requirements into UNet, rather than making significant changes within the existing stand-alone system for VCA. Current policy contains exclusions for VCA based on the stand-alone data collection process. This proposal includes policy changes associated with programming living VCA donation data collection instruments in UNet. **Table 4** summarizes the data collection instruments impacted by this proposal, and associated areas of policy that would be updated following programming in UNet.

Table 4. Data Collection Instruments to be Programmed in UNet

Data Collection Instrument	Description	Policies Impacted
Living Donor Feedback	• Collects data prior to donation surgery • Includes donor identification information and blood type	• *Policy 14.5.C Reporting of Living Donor Blood Type and Subtype* • *Policy 18.1B Timely Submission of Certain Data*
Living Donor Registration (LDR)	• Collects data when the living donor is discharged or 42 days following the transplant date, whichever is first • Includes clinical information and complications	• *Policy 18.1B Timely Submission of Certain Data* • *Policy 18.2 Timely Collection of Data*
Living Donor Follow-Up (LDF)	• Collects data around the six-month, one-year, and two-year anniversary of the donation date • Includes clinical information and complications	• *Policy 18.1B Timely Submission of Certain Data* • *Policy 18.2 Timely Collection of Data*
Donor Histocompatibility (DHS)	• Completed by the histocompatibility laboratory responsible for performing tissue typing for deceased and living donors • Includes histocompatibility typing results	• *Policy 18.1B Timely Submission of Certain Data*

This proposal does not include any changes to the Living Donor Feedback data collection instrument, but this form must be programmed in UNet in order for UNet to generate the LDR and LDF. OPTN *Policy 18: Data Submission Requirements* currently excludes VCA from requirements for timely submission of the LDR, LDF, and Living Donor Feedback data collection instruments by recovery hospitals. This proposal would remove these policy exclusions to require timely submission of living donor data collection instruments for all living VCA donors.

This proposal does not include any changes to the Donor Histocompatibility (DHS) data collection instrument. However, the policy changes associated with programming the DHS and Living Donor Feedback data collection instruments in UNet will impact operations for transplant programs and histocompatibility laboratories, as summarized in **Table 5**.

Table 5: Impact of Programming Certain VCA Data Collection Instruments in UNet

Policy Impacted	Current State	Future State
14.5.C Reporting of Living Donor Blood Type and Subtype	Living VCA donor blood type and subtype verification and reporting must be recorded in the living donor's medical record	Living VCA donor blood type and subtype verification and reporting will be recorded in UNet via the Living Donor Feedback
18.1 Data Submission Requirements	Living VCA donors are excluded from requirements for histocompatibility laboratories to submit the Donor Histocompatibility (DHS) data collection instrument	Histocompatibility laboratories will submit the DHS for living VCA donors in UNet

For all other organs, living donor blood type and subtype verification and reporting is documented in UNet via the Living Donor Feedback data collection instrument. Since VCA is not programmed in UNet, and submission of the VCA Living Donor Feedback data collection instrument has not been required by OPTN policies, OPTN *Policy 14: Living Donation* currently requires living donor blood type verification for VCA recoveries to be documented in the living donor's medical record. This proposal would remove this requirement since recovery hospitals will be able to conduct this verification and reporting via UNet.

OPTN *Policy 18: Data Submission Requirements* requires histocompatibility laboratories to submit Donor Histocompatibility (DHS) forms for all living and deceased donors,[46] though the DHS is not currently programmed in UNet for living VCA donors. This proposal would remove the exclusion for VCA contained in the companion proposal entitled *Programming VCA Allocation in UNet*, since histocompatibility laboratories will be able to submit the DHS for living VCA donors following programming in UNet. The policy exclusion in the companion proposal reflects the OPTN's plan to program deceased donor VCA and living donor VCA in UNet sequentially rather than concurrently.

The OPTN has a target implementation date of June 2022 to program all of these functions into UNet.

[46] Current OPTN policies state that the DHS should be submitted for "Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory," but the OPTN Board of Directors approved policy language in December 2019 stating that the DHS should be submitted for "each living and deceased donor." This language is expected to be implemented by December 2020. More information on this policy change is available on the OPTN website: https://optn.transplant.hrsa.gov/governance/public-comment/modify-data-submission-policies/

OPTN Data Collection Development Process

To develop this data collection proposal, the Committee established a VCA Living Donor Data Collection Workgroup comprised of members from the Committee and the OPTN Living Donor Committee (LDC). The Workgroup also included a living uterus donor and a subject matter expert representing the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. The LDC established a separate workgroup, the Living Donor VCA Workgroup, to work on updates to OPTN *Policy 14: Living Donation*.

The Committee collaborated with the DTAC to develop proposed data elements for infectious disease testing. The Committee also sought input and guidance from the OPTN Data Advisory Committee (DAC) throughout development of the proposal to improve data quality and to ensure that the proposed data elements are aligned with the OPTN Principles for Data Collection.[47] Following an initial endorsement from the DAC in February 2020, the proposed data elements were evaluated against the DAC's Data Element Standards of Review Checklist to ensure that the proposed data elements are relevant, available, reliable and usable. The Committee presented this evaluation to the DAC in May 2020. The DAC reviewed the proposed data elements and data definitions and supported the proposal. The Committee also reviewed relevant clinical literature to identify possible complications that may occur during and after uterus donation.[48,49]

NOTA and Final Rule Analysis

The Committee submits the following proposal for community feedback under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[50] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[51] and shall "…receive…such records and information electronically…"[52] The OPTN has been directed by the Secretary "to develop policies regarding organ donors and living organ donor recipients."[53] This proposal will allow the OPTN to collect more complete data on living VCA donors and maintain such data in the OPTN dataset.

The OPTN is providing the public with the opportunity to comment on these proposed policy changes in accordance with NOTA[54] and the OPTN Final Rule.[55]

[47] OPTN, "Principles of Data Collection."
[48] Azaan Ramani et al., "DUETS (Dallas UtErus Transplant Study): Complete report of 6-month and initial 2-year outcomes following open donor hysterectomy," *Clinical Transplantation* (2019): 7, https://doi.org/10.1111/ctr.13757.
[49] Liza Johannesson et al., "DUETS (Dallas UtErus Transplant Study): Early Outcomes and Complications of Robot-Assisted Hysterectomy for Licing Uterus Donors," *Transplantation* (2020), doi: 10.1097/TP.0000000000003211.
[50] 42 CFR §121.11(b)(2).
[51] 42 CFR §121.11(a)(1)(ii).
[52] 42 CFR §121.11(a)(1)(iii).
[53] Response to Solicitation on Organ Procurement and Transplantation Network (OPTN) Living Donor Guidelines, 71 Fed. Reg. 34946, 34948 (June 16, 2006).
[54] National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(I).
[55] OPTN Final Rule 42 CFR § 121.4 (b)(1), and (e).

Implementation Considerations

Member and OPTN Operations

To implement this proposal, the OPTN would need to modify OPTN data collection instruments and communicate the changes to the transplant community. The OPTN would also create help documentation for the new data elements to provide additional instruction for submitting these data, and the Committee would work with the OPTN to continue to refine the data element definitions throughout implementation of this proposal. Transplant hospitals would be required to become familiar with the new data requirements and how to access this information.

The target implementation timeline for this proposal is June 2022. This implementation timeline is longer than the standard 12-month implementation timeline to allow time for the federal Office of Management and Budget (OMB) to review and approve the data elements, and to synchronize implementation with a separate project to program deceased donor VCA allocation and data collection into UNet, which has a target implementation date of December 2021. Programming the VCA-specific modifications to the LDR and LDF in UNet, along with the DHS and VCA Living Donor Feedback, would commence following implementation of programming deceased donor VCA allocation in UNet. Proposed policy changes to support the operational decision to program deceased donor VCA allocation into UNet are outlined in a separate proposal released for public comment this cycle entitled *Programming VCA Allocation in UNet*.

Operations affecting the OPTN

This proposal would require the submission of official OPTN data that are not presently collected by the OPTN. As these data are proposed to be collected under §121.11(b)(2) of the OPTN Final Rule, after OPTN Board approval they would be submitted for OMB approval under the Paperwork Reduction Act of 1995. Once OMB-approved, the data would be maintained according to the OPTN System of Records Notice.[56] This would require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Once approved by OMB, the revisions to the LDR and LDF data collection instruments would be programmed into UNet. Help documentation and instructions would be updated to assist members with data submission.

Operations affecting Transplant Hospitals

This proposal would gather VCA donor data to better understand donor outcomes and protect donor safety and would apply to all living VCA donors. The largest scope of changes would be for living donor recovery hospitals supporting uterus transplant programs. VCA transplant programs would need to become familiar with these changes to data required by the OPTN. Transplant hospital staff would need to become familiar with the new data requirements and where to obtain these data from medical records. This proposal may add additional administrative burden, particularly for data collection related to living donor uterus transplantation, in the interest of promoting living donor and transplant recipient safety. Transplant hospitals would also conduct living donor blood type verification for VCA recoveries via UNet rather than documenting blood type via donor medical records.

[56] "System of Record Notice 09-15-0055," Health Resources and Services Administration, accessed June 4, 2020, https://www.hrsa.gov/about/privacy-act/09-15-0055.html

Operations affecting Histocompatibility Laboratories

Histocompatibility laboratories would need to submit Donor Histocompatibility data collection instruments for living VCA donors via UNet.

Operations affecting Organ Procurement Organizations

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

Projected Fiscal Impact

Projected Impact on Transplant Hospitals

The time and cost to implement these changes at transplant centers are minimal. Any resources for pre-donation/transplant data collection and entry is allowable on the Medicare Cost Report.

Additional data entry staff time will ensure complete and accurate data entry. Typically, programs utilize one or multiple staff to complete data entry for all organ programs. Staff and systems should be positioned with staff and ability to incorporate the VCA data entry into current workflow.

Data collection will be dependent on program volume and may vary year to year.

Implementation is estimated at one to three months.

This proposal standardizes VCA data to be collected similarly to other organ types, and creates overall clarity and efficiency in the data collection process for transplant centers.

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.

Projected Impact on the OPTN

Preliminary estimates indicate that this would be a large project for the OPTN to develop and implement as approximately 1,000 hours may be needed for IT programming, development of help documentation, notification to OPTN staff and the transplant community regarding these changes, and research support for these efforts.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the

program."[57] This proposal will not change the current routine monitoring of OPTN members. Any data entered in UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[58] The OPTN will report the following metrics to the Committee after implementation at six months, one year, and as needed.

- Number and percent of living VCA donors with LDR and LDF forms submitted to the OPTN
- Number and percent of living VCA donors with complications reported to the OPTN on the LDR and LDF

Conclusion

This proposal would require data collection on living VCA donors and would add new data elements to OPTN living donor data collection instruments in order to promote living donor and transplant recipient safety. These new data collection requirements would improve the OPTN's ability to monitor patient safety, as data on living VCA donors is currently only submitted to the OPTN voluntarily. This proposal also contains policy changes associated with programming living VCA donor data collection instruments in UNet.

There are two other public comment proposals that impact VCA. This proposal was developed in conjunction with the Living Donor Committee's related proposal, *Modify Living Donation Policy to Include Living VCA Donors.* The VCA Committee is also sponsoring a separate proposal, *Programming VCA Allocation in UNet,* for policy changes associated with programming deceased donor VCA allocation and data collection in UNet. Proposed changes to the LDR and LDF in this proposal would also be programmed into UNet versus the current stand-along system. This proposal would have a target implementation of 2022, following implementation of programming VCA allocation for deceased donors in UNet, which is slated for December 2021.

The Committee seeks feedback on the following questions:

- Are there any data elements listed in **Appendix 2** that should not be added to the LDR or LDF?
- Are the data definitions outlined in **Appendix 3** clear enough to ensure consistent data entry?
- Should any of the proposed data elements for living uterus donors (e.g. new onset psychological symptoms) apply to all or other VCA living donors?

[57] 42 CFR §121.8(a)(7)
[58] 42 CFR §121.8(a)(6)

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.

14.5.C Reporting of Living Donor Blood Type and Subtype

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~~

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

18.1 Data Submission Requirements

18.1.A Accurate Submission of Data

OPTN members must submit accurate data to the OPTN Contractor must maintain documentation demonstrating the accuracy of all data submitted to the OPTN.

18.1.B Timely Submission of Certain Data

Members must submit data to the OPTN Contractor according to Table 18-1.

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor ~~This does not apply to living VCA donors~~
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPO	*Death Notification Registration (DNR)*	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential Transplant Recipient* (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital ~~This does not apply to VCA donor organs~~
Recovery Hospitals	*Living Donor Feedback*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the Recovery Hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital ~~This does not apply to VCA donor organs~~
Recovery Hospitals	*Living Donor Follow-up* (LDF)	Either: • 90 days after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency.	Each living donor organ recovered at the hospital This does not apply to ~~VCA,~~ domino donor, and non-domino therapeutic donor organs. Non-submission of the full LDF is acceptable during the COVID-19 emergency.

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency • 30 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.1.C Changes to Submitted Data

Upon expiration of the corresponding timeframe listed in Table 18-1, data submitted using the following instruments are considered final:

- Deceased Donor Registration (DDR)
- Donor Histocompatibility (DHS)
- Recipient Histocompatibility (RHS)
- Transplant Candidate Registration (TCR)
- Transplant Recipient Registration (TRR)
- Living Donor Registration (LDR)
- Transplant Recipient Follow-up (TRF)
- Living Donor Follow-up (LDF)

Changes to final data will not be permitted unless the member reports, within the data collection system prior to making the changes, both the approval of the member's official OPTN Representative (or designee) and the reason for the changes.

18.1.D Reporting

The Data Advisory Committee must report to the Board of Directors at least annually all of the following:

- Data submission compliance rates;
- The frequencies of data change following submission and reasons reported; and
- Other relevant information identified by the Committee.

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. **Error! Reference source not found.** sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first. ~~This does not apply to VCA transplants.~~
Recovery hospital	*Living donor follow-up* (LDF)	Either: • 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency. ~~This does not apply to VCA transplants.~~ Non-submission is acceptable during the COVID-19 emergency.

Appendix 1: *Current LDR and LDF Data Collection Summary*

Data Elements on LDR Instrument	All Organs	Kidney	Liver	Lung
General Information				
Provider information (Recipient Center)	X	X	X	X
Donor information (Donor ID, blood type, donor type, demographics)	X	X	X	X
Socio-demographic information (level of education, work status, functional capacity)	X	X	X	X
Pre-Donation Clinical Information				
Viral detection (HIV, CMV, HBV, HCV, EBV)	X	X	X	X
Height/Weight	X	X	X	X
History of Cancer	X	X	X	X
History of Cigarette Use/Other Tobacco Used	X	X	X	X
Diabetes and treatment	X	X	X	X
Total Bilirubin			X	
SGOT/AST			X	
SGPT/ALT			X	
Alkaline Phosphatase			X	
INR (International Normalized Ratio)			X	
Liver Biopsy			X	
Serum Albumin			X	
Serum Creatinine		X	X	
History of Hypertension/Method of Control		X		
Preoperative Blood Pressure – Systolic and Diastolic		X		
Urinalysis – urine protein or protein-creatinine ratio		X		
FVC (Forced Vital Capacity) % predicted				X
FEV1 (Forced Expiratory Volume at One Second) % predicted				X
FEF (Forced Expiratory Flow) (25-75%) % predicted				X
TLC (Total Lung Capacity) % predicted				X
Diffusing lung capacity corrected for alveolar volume % predicted				X
PaO_2 on room air				X
Surgical Information				
Type of transplant graft		X	X	X
Intended procedure type or procedure type		X		X
Conversion from [laparoscopic or thoracoscopic] to open		X		X
Intraoperative complications, including anesthetic complications				X
Post-Operative Information				
Date of initial discharge, donor status (living or dead), date last seen	X	X	X	X
Non-Autologous Blood Administration	X	X	X	X
Biliary Complications			X	
Vascular Complications Requiring Intervention		X	X	
Other Complications Requiring Intervention		X	X	
Reoperation		X	X	
Any Readmission After Initial Discharge		X	X	X
Other Interventional Procedures		X	X	
Post-operative complications during the initial hospitalization				X
Weight	X	X	X	X
Total Bilirubin			X	
SGOT/AST			X	
SGPT/ALT			X	
Alkaline Phosphatase			X	

Data Elements on LDR Instrument	All Organs	Kidney	Liver	Lung
INR (International Normalized Ratio)			X	
Serum Albumin			X	
Serum Creatinine		X	X	
Post-operative Blood Pressure – Systolic and Diastolic		X		
Urinalysis – urine protein or protein-creatinine ratio		X		
Donor developed hypertension requiring medication		X		
Organ Recovery				
Organ(s) recovered, organ recovery date, recovery/work-up facilities	X	X	X	X
Recipient Name	X	X	X	X

Data Elements on LDF Instrument	All Organs	Kidney	Liver	Lung
General Information				
Provider information (Recipient Center)	X	X	X	X
Donor information (Donor ID, blood type, donor type, demographics)	X	X	X	X
Socio-demographic information (level of education, work status, functional capacity)	X	X	X	X
Clinical Information				
Current weight	X	X	X	X
ER or urgent care visit related to donation since last follow-up	X	X	X	X
Total Bilirubin, SGOT/AST, SGPT/ALT, Alkaline Phosphatase, Serum Albumin, Serum Creatinine, INR, Platelet count			X	
Serum Creatinine, Blood pressure (systolic/diastolic), urinalysis, donor developed hypertension requiring medication		X		
Maintenance dialysis		X		
Diabetes and treatment		X		
Activity Level				X
Chronic Incisional Pain				X
Complications				
Has the donor been readmitted since [last date seen] – if yes, date, and specify reason	X	X	X	X
Kidney Complications since [last date seen]		X		
Liver Complications since [last date seen]			X	
Complications since [last date seen]	X	X	X	X
Recipient Information				
Name, transplant date, SSN	X	X	X	X

Appendix 2: *Proposed Modifications to VCA LDR and LDF Data Collection*

Table 1: Proposed Data Elements to Add to the LDR

Data Elements	Justification
Pre-Donation Uterus Clinical Information	
Human Papillomavirus (HPV) - cervical specimen only by DNA or mRNA	Because HPV infection could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment).
Herpes Simplex Virus (HSV) 1/2 (IgG)	Because herpes infection could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment).
Gonorrhea (NAT)	Because gonorrhea infection could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment).
Chlamydia (NAT)	Because chlamydia infection could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment.
Vaginal Candidiasis (collected at the time of evaluation)	Because vaginal candidiasis infection could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment).
Vaginal Candidiasis (collected at the time of donation)	The Committee proposes collecting these data both at the time of evaluation and at the time of donation because candida naturally occurs in the vagina and an active infection could threaten the success of the transplant.[59] At the time of evaluation, the donor can be treated prior to donation; at the time of donation, collecting these data allows the recovery hospital to confirm that the donor does not have an active infection.
Bacterial Vaginosis (*Gardnerella vaginalis*)	Because bacterial vaginosis could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment). Infection has been associated with adverse pregnancy outcomes like fetal demise, premature delivery, and low birth weight.[60,61]
Trichomoniasis	Because trichomoniasis could impact the health of the recipient and the outcome of a uterus transplant, it is important to ensure this

[59]Denise Grady, "Yeast Infection Led to Removal of Transplanted Uterus," *The New York Times,* April 8, 2016, https://www.nytimes.com/2016/04/09/health/yeast-infectionled-to-removal-of-transplanted-uterus.html.
[60] Maria Romoren et al., "Trichomoniasis and bacterial vaginosis in pregnancy: inadequately managed with the syndromic approach," *Bulletin of the World Health Organization* 85, no. 4 (2007): 245-324, https://www.who.int/bulletin/volumes/85/4/06-031922/en/.
[61] Elizabeth M. McClure and Robert L. Goldenberg, "Infection and stillbirth," *Seminars in Fetal and Neonatal Medicine* 14, no. 4 (2009): 182-189, doi: 10.1016/j.siny.2009.02.003.

	testing is completed and to know the results of the test (relevant for patient safety, member compliance, and outcome assessment). Infection has been associated with adverse pregnancy outcomes like fetal demise, premature delivery, and low birth weight.[62,63]
Other Testing	Collecting data on other testing is important given that uterus transplantation is a novel field, so this data element will allow the OPTN to identify any other tests commonly used by transplant programs.
Uterine Imaging	Uterine imaging should be conducted prior to living donation to check for any structural abnormalities, so it is important to collect these data to confirm whether imaging was conducted and if there were any notable findings (relevant for patient safety and outcome assessment).
Gravidity	Gravidity is directly related to the desired outcome of a uterus transplant (pregnancy), so it is important to collect these data to assess outcomes. The Committee proposes collecting this information as well as "prior full term live births" because these numbers can be very different.
Parity	Parity is directly related to the desired outcome of a uterus transplant (pregnancy and birth of a child), so it is important to collect these data to assess outcomes. The Committee proposes collecting this information as well as "prior full term live births" because these numbers can be very different. The Workgroup also noted that there is not consensus in the community as to whether nulliparous donors should be accepted, so if some programs are accepting these donors, it would be important to collect information on their outcomes.
Spontaneous Abortion	Since the purpose of a uterus transplant is to achieve a successful pregnancy, data collection on spontaneous abortion (miscarriage) is relevant as it may be related to the function of the organ to be donated. The Committee noted that transplant programs may be concerned that a uterus from a donor with a high ratio of miscarriages to live births would not function for a recipient (in terms of achieving the desired outcome of a live birth).
Induced Abortion	The Committee noted that some transplant programs have not been willing to accept living donors with a significant history of instrumentation of the endometrial cavity. It is important for the OPTN to collect these data to understand whether it has an impact on transplant recipient outcomes.
Prior Full Term Live Births	Prior full term live births is directly related to the desired outcome of a uterus transplant (pregnancy and birth of a child), so it is important to collect these data to assess outcomes.
Pre-Donation All VCA Clinical Information	
Toxoplasma IgG	Collecting this information is important for any VCA transplant that includes skeletal muscle. Collecting this information is also important for uterine transplant due to potential for reactivation under immunosuppression and to infect a fetus. Once a person is infected, the *Toxoplasma gondii* tachyzoites can go to any part of the body but have a propensity for skeletal muscle, cardiac muscle, and brain. For the same reason, VCA recipients of transplants that contain skeletal

[62] Maria Romoren et al., "Trichomoniasis and bacterial vaginosis in pregnancy: inadequately managed with the syndromic approach," *Bulletin of the World Health Organization* 85, no. 4 (2007): 245-324, https://www.who.int/bulletin/volumes/85/4/06-031922/en/.
[63] Elizabeth M. McClure and Robert L. Goldenberg, "Infection and stillbirth," *Seminars in Fetal and Neonatal Medicine* 14, no. 4 (2009): 182-189, doi: 10.1016/j.siny.2009.02.003.

	muscle are at high risk if the donor had a *T. gondii* infection. The uterine transplant is at risk like other organs but poses additional concerns since fetal infection (congenital toxoplasmosis) will have lifelong implications for developmental delay and vision (relevant for patient safety, member compliance, and outcome assessment).
Uterus Surgical Information	
Intended Procedure Type	The relative efficacy and safety of various procedure types is unknown, given the small number of procedures conducted, so collecting intended procedure type is relevant to patient safety and outcomes assessment.
Conversion from Robotic to Open	The relative efficacy and safety of various procedure types is unknown, given the small number of procedures conducted, so collecting information on the procedure type, including whether the surgery was converted from a robotic surgery to an open surgery, is relevant to patient safety and outcomes assessment.
Operative Time (surgical time from skin to skin)	Operative time may be associated with outcomes and may vary by procedure type, so collecting these data is relevant to patient safety and outcomes assessment.
Ovaries Removed	While it is not recommended to remove ovaries as part of a living uterus donation, it is important to document if ovaries are removed because it can have a significant impact on the donor's health.
Intra-Operative Complications	Collecting data on intra-operative complications will allow the OPTN to identify trends that impact living donor safety and transplant outcomes.
Ureter Injury	Ureter injury is an intra-operative complication that has been identified in clinical literature in conjunction with living uterus donation.[64] Collecting these data is relevant to monitoring trends and identifying risks for living donors.
Anesthetic Complications	It is important to collect data on anesthetic complications to identify potential risks for living donor safety.
Other Complications	It is important to collect data on other complications arising during surgery for living uterus donation because this type of donation is novel and there is not yet substantial literature on issues that may arise that threaten either living donor safety or recipient outcomes.
Other VCA Surgical Information	
Intra-Operative Complications	Collecting data on intra-operative complications will allow the OPTN to identify trends that impact living donor safety and transplant outcomes.
Uterus Post-Operative Information	
Length of ICU Stay (days)	Collecting data on ICU stay will allow the OPTN to monitor the risks of living uterus donation and convey that risk to potential living donors.
Uterus-Related Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	
Complications Requiring Intervention	It is important to collect data on other post-operative complications for living uterus donation because this type of donation is novel and there is not yet substantial literature on issues that may arise that threaten living donor safety.
Other VCA Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	
Complications Requiring Intervention	It is important to collect data on other post-operative complications for living donation of other VCA types because this type of donation is

[64] Ramani et al., "DUETS (Dallas UtErus Transplant Study)," 2.

	novel and there is not yet substantial literature on issues that may arise that threaten living donor safety.
All VCA Post-Operative Complications	
Reoperation	It is important to collect data on reoperation to allow the OPTN to monitor the risks of living VCA donation and convey that risk to potential living donors.
Any Readmission After Initial Discharge	It is important to collect data on readmission following donation to allow the OPTN to monitor the risks of living VCA donation and convey that risk to potential living donors.

Table 2: Proposed Data Elements to Add to the LDF

Data Elements	Justification
Uterus Clinical Information	
Complications Since Uterus Donation	It is important to collect data on complications following living uterus donation because this type of donation is novel and there is not yet substantial literature on issues that may arise that threaten living donor safety. The complications listed in the data definition were identified in medical literature.[65]
Menopausal Symptoms	Causing menopause has major implications for overall health and cardiovascular morbidity over time, so it is important for the OPTN to monitor whether living uterus donors experience menopause after donation as this is not a desired outcome for the donor (patient safety).
New Onset Psychological Symptoms	Several studies have documented psychosocial complications following living donation of other organs,[66, 67, 68, 69] so the Committee believes it is important for the OPTN to collect this information in order to monitor for trends and to inform the expectations of living uterus donors (patient safety).
Complications Since Other VCA Donation	It is important to collect data on complications following living donation of other VCA types because this type of donation has not been reported in the Unites States and there is not yet substantial literature on issues that may arise that threaten living donor safety.

[65] Ramani et al., "DUETS (Dallas UtErus Transplant Study)," 2.
[66] Ummel, Achille, and Mekkelholt, "Donors and recipients of living kidney donation," 8.
[67] K.K. Clemens et al., "Psychosocial health of living kidney donors," 2965.
[68] Jowsey and Scheekloth, "Psychosocial factors in living organ donation," 193.
[69] Parikh, Ladner, Abecassis, and Butt, "Quality of life for donors after living donor liver transplantation," 1354-1355.

Appendix 3: *Proposed Data Definitions*

Living Donor Registration (LDR)

Pre-Donation All VCA Clinical Information

Toxoplasma IgG: Screening for toxoplasma is a way to increase transplant recipient safety by potentially decreasing the number of unexpected transmissions of *toxoplasma gondii*. Select the result of the test:

Positive
Negative
Not Done
UNK/Cannot Disclose

Pre-Donation Uterus Clinical Information

Human Papillomavirus (HPV) cervical specimen only by DNA or mRNA: HPV (Human papillomavirus) is a sexually transmitted infection that can cause health problems like genital warts and cancer. There are several types of HPV and most do not lead to cancer, but certain types of genital HPV can cause cancer in the lower part of the uterus that connects to the vagina (cervix). Select the result of the test:

Positive
Negative
Not Done
UNK/Cannot Disclose

Herpes Simplex Virus (HSV) 1/2 (IgG antibody test): Herpes simplex virus (HSV) is a sexually transmitted disease. There is some research that suggests that genital herpes infection may lead to miscarriage or increase the likelihood of preterm birth. Genital herpes can cause painful genital sores and can be severe in people with suppressed immune systems. Select the result of the test:

Positive
Negative
Not Done
UNK/Cannot Disclose

Gonorrhea (NAT): Gonorrhea is a sexually transmitted bacterial infection that can cause pelvic inflammatory disease and damage reproductive organs. Gonorrhea can also be transmitted congenitally and cause serious health problems for a newborn child. Select the result of the test. If positive, select Yes if the patient was treated for gonorrhea and No if the patient was not treated for gonorrhea.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Chlamydia (NAT): Chlamydia is a sexually transmitted bacterial infection that can cause pelvic inflammatory disease and damage reproductive organs. Chlamydia can also be transmitted congenitally and cause health problems for a newborn child. Select the result of the test. If positive, select Yes if the patient was treated for chlamydia and No if the patient was not treated for chlamydia.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Vaginal Candidiasis (collected at the time of evaluation): Vaginal candidiasis is a fungal infection that is more likely to occur in immunocompromised individuals and may impact the outcome of a uterus transplant. Select the result of the test. If positive, select Yes if the patient was treated for vaginal candidiasis and No if the patient was not treated for vaginal candidiasis.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Vaginal Candidiasis (collected at the time of donation): Vaginal candidiasis is a fungal infection that is more likely to occur in immunocompromised individuals and may impact the outcome of a uterus transplant. Select the result of the test. If positive, select Yes if the patient was treated for vaginal candidiasis and No if the patient was not treated for candidiasis.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Bacterial Vaginosis (*Gardnerella vaginalis*): Bacterial vaginosis is a type of vaginal inflammation caused by the overgrowth of bacteria naturally found in the vagina. Bacterial vaginosis can increase the likelihood of preterm birth and low birth weight. Select the result of the test. If positive, select Yes if the patient was treated for bacterial vaginosis and No if the patient was not treated for bacterial vaginosis.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Trichomoniasis: Trichomoniasis is a sexually transmitted disease caused by infection with a protozoan parasite. Trichomoniasis can increase the likelihood of preterm birth and low birth weight. Select the result of the test. If positive, select Yes if the patient was treated for trichomoniasis and No if the patient was not treated for trichomoniasis.

Positive
Negative
Not Done
UNK/Cannot Disclose

If positive, was the patient treated? Yes/No

Other testing: Specify other testing conducted for infectious diseases. Select the result of the test.

Type of test - specify:

Positive
Negative
Not Done
UNK/Cannot Disclose

Uterine imaging: Uterine imaging can be conducted via various tests including magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), or computerized tomography (CT), among others. Abnormal findings may include retroverted uterus, double uterus, or other anatomical abnormalities. Indicate the type of imaging used:

MRI/MRA
CT
Other, specify:

If imaging was conducted, indicate any abnormal findings:

Gravidity: Gravidity is the number of times a patient has been pregnant, regardless of pregnancy outcome. Enter the gravidity.

Parity: Parity is the number of pregnancies reaching 20 weeks and 0 days of gestation or beyond, regardless of the number of fetuses or outcomes. Enter the parity.

Spontaneous Abortion: Spontaneous abortion is non-induced embryonic or fetal death or passage of products of conception before 20 weeks gestation (miscarriage). Enter the number of spontaneous abortions.

Induced Abortion: Induced abortion is termination of pregnancy for medical or elective reasons. Enter the number of induced abortions.

Prior Full Term Live Births: Prior full term live births is the number of live births at 39 weeks gestation or later. Enter the number of prior full term live births and indicate the type of delivery for all prior births.

Total number of births:
Number of vaginal deliveries:
Number of deliveries by C-section:

Uterus Surgical Information

Intended Procedure Type: Select the intended procedure type.

Robotic
Open
Hybrid

Conversion from Robotic to Open: If Robotic was selected for Intended Procedure Type, and there was a conversion from robotic to open procedure, select Yes. If there wasn't a conversion, select No.

Operative Time (surgical time from skin to skin): Operative time is the time taken from skin incision to completion of skin closure. Enter the start time and end time.

Ovaries Removed: If ovaries were removed during uterus donation, select Yes. If the donor's ovaries were not removed, select No. If the donor's ovaries were absent at the time of uterus donation, select Not applicable – ovaries not present at donation.

Intra-Operative Complications: Intra-operative complications refer to complications occurring during operative time. If the donor experienced intra-operative complications, select Yes. If not, select No.

Ureter Injury: Ureter injury refers to damage to the ureter.

If a ureter injury occurred during surgery, select Yes. If not, select No.
If yes, indicate whether a unilateral or bilateral injury occurred (Yes/No/Other).
Was the injury corrected? Select Yes/No.

Anesthetic Complications: If anesthetic complication occurred, enter the complication.

Other Complications: If other complications occurred during surgery, enter the complication.

Other VCA Surgical Information

Intra-Operative Complications: Intra-operative complications refer to complications occurring during operative time. If the donor experienced intra-operative complications, select Yes. If not, select No. If Yes, indicate the complications experienced by the donor.

Uterus Post-Operative Information

Length of ICU Stay (days): The length of stay in the intensive care unit (ICU) is measured from the day that the patient entered the ICU to the day that the patient exited the ICU, counting both the day of entry and the day of exit. Enter the number of days spent in the ICU.

Uterus Related Post-Operative Complications

Complications Requiring Intervention: If the donor experienced complications requiring intervention following donation but prior to discharge or 6 weeks post-donation, whichever comes first, select Yes. If not, select No. If unknown, select UNK. If Yes, indicate the complications experienced by the donor. If the donor experienced complications that are not listed, select Other and enter the complication(s).

Wound Infection
Ureterovaginal Fistula
Nocturia
Meralgia Paresthetica
Bladder Hypotonia
Other – Specify:

Other VCA Related Post-Operative Complications

Complications Requiring Intervention: If the donor experienced other complications requiring intervention following donation but prior to discharge or 6 weeks post-donation, whichever comes first, select Yes. If not, select No. If Yes, enter the complications.

All VCA Post-Operative Complications

Reoperation: If the donor required reoperation following donation but prior to discharge or 6 weeks post-donation, whichever comes first, select Yes. If not, select No. If unknown, select UNK.

If Yes, specify reason for reoperation (during first six weeks):
Enter the date for each reason using the standard 8-digit format of MM/DD/YYYY.

Any Readmission After Initial Discharge: If the donor required any readmission following donation but prior to discharge or 6 weeks post-donation, whichever comes first, select Yes. If not, select No. If unknown, select UNK.

If yes, specify reason for readmission (during first six weeks):
Enter the date of the first readmission using the standard 8-digit format of MM/DD/YYYY.

Living Donor Follow-up (LDF)

Complications - Uterus

Complications Since Uterus Donation: If the donor experienced complications since the last report, select Yes. If not, select No. If unknown, select UNK. If Yes, indicate the complications experienced by the donor. If the donor experienced complications that are not listed, select Other and enter the complication(s).

Wound Infection
Ureterovaginal Fistula
Nocturia
Meralgia Paresthetica
Bladder Hypotonia

Dyspareunia
Sexual Dysfunction
Pain
    If yes: chronic or intermittent/transient
    Location:
        Abdominal
        Pelvic
        Vaginal
        Other
Urinary Tract Infection
Other – specify:

Menopausal Symptoms: If the donor has developed menopausal symptoms since the last report, select Yes. If not, select No. If unknown, select UNK. If Yes, indicate the symptoms experienced by the donor. If the donor developed other menopausal symptoms that are not listed, select Other and specify.

Hot flashes
Mood swings
Other – specify:

New Onset Psychological Symptoms: If the donor developed new psychological symptoms following uterus donation, select Yes. If the donor did not develop new psychological symptoms, select No. If unknown, select UNK. If Yes, indicate the symptoms experienced by the donor. If the donor developed new psychological symptoms that are not listed, select Other and specify.

Anxiety
Depression
Change of mood
Change of eating habits
Suicidal ideation
Other – specify:

Complications - Other VCA

Complications Since Other VCA Donation: If the donor experienced complications since the last report, select Yes. If not, select No. If unknown, select UNK. If Yes, indicate the complications experienced by the donor. If the donor experienced complications that are not listed, select Other and enter the complication(s).

Pain
    If yes: chronic or intermittent/transient
    Location – specify:
Loss of function related to donation – specify:
Other – specify