OPTN

Mini-Brief

Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts

OPTN Vascularized Composite Allograft Transplantation Committee

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Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts

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Executive Summary

At their June 6, 2016 meeting, the OPTN Board of Directors approved a proposal from the Vascularized Composite Allograft (VCA) Transplantation Committee entitled *List Covered Body Parts Pertaining to VCA*.[1,2] This proposal was developed in compliance with the Final Rule requirement to "identify all covered body parts in any policies specific to vascularized composite allografts."[3] Implementation of that proposal was scheduled for June 2021 in conjunction with implementation of updated VCA transplant program membership requirements.[4,5]

[1] Executive Summary of the OPTN Board of Directors Meeting, June 6-7, 2016, OPTN, accessed March 30, 2021, https://optn.transplant.hrsa.gov/media/1953/executive_summary_06-2016.pdf.
[2] "List Covered Body Parts Pertaining to VCA," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/1879/vca_policynotice_01_201606.pdf.
[3] 42 CFR §121.4(e)(3)
[4] "VCA transplant programs to begin reapplication period Oct. 8 ahead of new Bylaws," September 22, 2020, OPTN, accessed March 30, 2021, https://optn.transplant.hrsa.gov/news/vca-transplant-programs-to-begin-reapplication-period-oct-8-ahead-of-new-bylaws/.
[5] "Vascularized Composite Allograft Membership Changes," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf.

Following a review for Final Rule compliance in December 2020, the OPTN recognized a need to modify the list of covered body parts. Around the same time, the OPTN received questions from the transplant community as to whether certain clinical procedures involving body parts included in the list of covered body parts are considered solid organ transplants. This proposed clarification of VCA-specific policies and bylaws addresses the concerns regarding compliance with the Final Rule as well as the questions raised by the transplant community.

Purpose

This proposal separates the list of body parts covered by VCA-specific policies and bylaws from the definition of "Vascularized Composite Allograft" to clarify that the list of covered body parts does not narrow or expand the scope of the federal definition of VCA as an organ.[6] This approach aligns with the Final Rule requirement for the OPTN to "identify all covered body parts in any policies specific to vascularized composite allografts."[7] This proposal also offers additional clarification sought by the transplant community regarding whether certain clinical procedures are considered VCA transplants. This proposal is considered a clarification because it does not change the intent of, or add to, the existing policy.

Background

At their June 6, 2016 meeting, the OPTN Board of Directors (Board) approved a proposal from the Vascularized Composite Allograft (VCA) Transplantation Committee entitled *List Covered Body Parts Pertaining to VCA*.[8,9] This proposal was developed to meet a requirement in the Final Rule for the OPTN to "identify all covered body parts in any policies specific to vascularized composite allografts."[10] Implementation of this policy language was scheduled for June 2021 in conjunction with implementation of updated VCA transplant program membership requirements.[11,12] The relevant policy language in *Policy 1.2 Definitions* approved by the Board in 2016 is shown below:

> **Vascularized Composite Allograft (VCA)**
>
> A transplant involving any body parts that meet *all* nine of the following criteria:
>
> 1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
> 2. Containing multiple tissue types.
> 3. Recovered from a human donor as an anatomical/structural unit.
> 4. Transplanted into a human recipient as an anatomical/structural unit.
> 5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
> 6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
> 7. Not combined with another article such as a device.
> 8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
> 9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

[6] 42 CFR §121.2
[7] 42 CFR §121.4(e)(3)
[8] Executive Summary of the OPTN Board of Directors Meeting, June 6, 2016, OPTN, accessed March 30, 2021, https://optn.transplant.hrsa.gov/media/1953/executive_summary_06-2016.pdf.
[9] "List Covered Body Parts Pertaining to VCA," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/1879/vca_policynotice_01_201606.pdf.
[10] 42 CFR §121.4 (e)(3)
[11] "VCA transplant programs to begin reapplication period Oct. 8 ahead of new Bylaws," September 22, 2020, OPTN, accessed March 30, 2021, https://optn.transplant.hrsa.gov/news/vca-transplant-programs-to-begin-reapplication-period-oct-8-ahead-of-new-bylaws/.
[12] "Vascularized Composite Allograft Membership Changes," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf.

The following body parts are considered VCAs:

- Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap)
- 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 nine numbered criteria listed reflect the federal definition of VCA as established in the Final Rule [13] and were implemented in OPTN *Policy 1.2 Definitions* in 2014.[14,15,16] The underlined list of "body parts [that] are considered VCAs" reflect the list of covered body parts that was approved by the Board in June 2016 and was scheduled for implementation in June 2021.

Concerns Regarding Compliance with the Final Rule

Following a review for Final Rule compliance in December 2020, the OPTN recognized a need to modify the list of covered body parts. HRSA notified the OPTN that the list of covered body parts does not comply with the Final Rule. The notification read as follows:[17]

1. *In order to conform with HHS regulatory requirements, the 2016 definition of VCA needs a slight correction to make it clear that the list of body parts provided in the definition does not narrow the scope of the regulatory definition of VCAs as organs. For example, the introductory language before the list of body parts could be modified to make clear that this list is a non-exclusive list of VCAs (since any body part that meets the regulatory definition is a VCA and an organ by virtue of the regulatory definition).*

   So long as this correction to the 2016 definition is made, the overall VCA definition referenced in the living donor VCA policy document does not need to be modified…

2. *Any VCA-specific policy, such as the living donor VCA policy,[18] must identify covered body parts. The body parts can be listed in the VCA-specific policy or included by reference to another OPTN definition. The living donor VCA policy language attempts to do this through a*

[13] 42 CFR §121.2
[14] Executive Summary of the OPTN Board of Directors Meeting, June 23-24, 2014, OPTN, accessed March 31, 2021, https://optn.transplant.hrsa.gov/media/1794/executive_summary_06-2014.pdf.
[15] "Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)," Public Comment Proposal, OPTN, accessed March 31, 2021, https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.
[16] Organ Procurement and Transplantation Network Policies, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.
[17] Christopher McLaughlin, Email to UNOS staff, December 4, 2020.
[18] The described "living donor VCA policy" refers to the proposed policy language in the OPTN briefing paper "Modify Living Donation Policy to Include Living VCA Donors." As of April 2021, this policy language has not been approved by the OPTN Board of Directors but the language cited is available on the OPTN website, accessed on April 23, 2021: https://optn.transplant.hrsa.gov/media/4199/bp_202012_modify-living-donor-policy-to-include-living-vca-donors.pdf. The Living Donor Committee is proposing modifications to this language to align with this clarification for the Board to consider in June 2021.

reference to the 2016 definition, but the list in the 2016 definition does not provide enough specificity to serve this purpose. Table 14-4 references living genitourinary and non-genitourinary "VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2." Such a cross-reference theoretically would be OK, except that the list of organs provided in Policy 1.2 is not exclusive (using "including, but not limited to" language). Because the living donor VCA policy is a VCA-specific policy, the specific body parts must be identified in order to satisfy section 121.4(e)(3). This can be done either through a tweak to the living donor VCA policy language (such as by referencing covered body parts in Table 14.4D) or more broadly by modifications to the 2016 definition of VCAs.

Questions from the Transplant Community

Around the same time, the OPTN received questions from the transplant community as to whether certain clinical procedures are considered VCA transplants. In particular, members sought clarification as to whether gland transplants are considered VCA transplants if the gland is minced or fragmented prior to implantation into the recipient. This approach has been used for transplantation of parathyroid and adrenal glands, and the gland fragments were implanted into the recipients' forearm or abdominal muscle rather than the usual anatomic location of the glands.[19,20] Meeting materials and working documents from 2015 and 2016 indicate the VCA Committee's awareness that gland transplants would only be considered VCA transplants if they were transplanted with a primary vascularization in order to meet the first criterion in the federal definition of a VCA, which states that VCA means a body part "that is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation."[21, 22]

Additionally, as VCA transplant programs were submitting new applications for implementation of the updated membership requirements,[23] a question arose as to where chest wall would fall among the list of covered body parts. Staff documents from 2016 indicate that the VCA Committee intended for chest wall to be covered under musculoskeletal composite graft segment.[24]

Proposal

This proposed clarification of VCA-specific policies and bylaws addresses concerns regarding compliance with the Final Rule, as well as questions raised by the transplant community.

Changes to Address Compliance with the Final Rule

To make it clear that the list of body parts provided in the *Policy 1.2* definition of VCA does not narrow or expand the scope of the regulatory definition of VCAs as organs, the VCA Committee (Committee) proposes separating the list of covered body parts from the definition of "Vascularized Composite Allograft." The Committee proposes defining "Covered Vascularized Composite Allograft body parts

[19] Ayman Agha, Marcus Nils Scherer, and Christian Moser, et al. "Living-donor parathyroid allotransplantation for therapy-refractory postsurgical persistent hypoparathyroidism in a nontransplant recipient – three year results: a case report," *BMC Surgery* 16 (2016): 51. https://doi.org/10.1186/s12893-016-0165-y

[20] E. Grodstein, M.A. Hardy, and M.J. Goldstein. "A case of human intramuscular adrenal gland transplantation as a cure for chronic adrenal insufficiency," *American Journal of Transplantation* 10 (2010): 431-433. doi: 10.1111/j.1600-6143.2009.02929.x

[21] OPTN Vascularized Composite Allograft Transplantation Committee, Meeting Summary, OPTN, December 9, 2020, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/4295/20201209_vca_summary.pdf.

[22] 42 CFR §121.2

[23] "Vascularized Composite Allograft Membership Changes," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf.

[24] "Covered Body Parts Reference List," OPTN, Staff document dated December 7, 2016.

(covered VCAs)" separately in *Policy 1.2 Definitions* to clarify that the body parts listed are those VCAs covered by OPTN Policies and Bylaws.

To increase the specificity of the list of covered body parts and to make the list exclusive, the Committee proposes removing the "including, but not limited to" language and using a table format to clarify which "covered VCAs" are covered under each VCA "type." This format preserves the eight VCA types identified in the original list of covered body parts. The Committee proposes some minor modifications to the covered VCAs under each VCA type to adjust for elimination of the "including, but not limited to," language (see **Table 1**). These modifications align with the Committee's original intent in developing the list of covered body parts approved by the Board in 2016.

Table 1: Changes to the List of Covered Body Parts

Policy Language	Proposed Clarification		Justification
Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap)	**Type**	Upper limb	• Removed "radial forearm flap" as it is encompassed by "any group of vascularized body parts from the upper limb" • The Committee discussed other approaches for defining the anatomy of the upper limb but felt this description was most apt since grafts used for upper limb transplants can vary in terms of the size of the graft and the anatomic structures included
	Covered VCA(s)	Any group of vascularized body parts from the upper limb	
Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid)	**Type**	Head and neck	• Removed "including underlying skeleton and muscle" because a partial face transplant may not include a skeletal component and the Committee did not want this language to exclude face transplants without skeletal components • Added "vascularized" in front of "parathyroid gland" and "thyroid" to emphasize that such body parts are only considered VCA transplants if they meet the criteria in the Final Rule definition of VCA • Added "any other vascularized body parts from the head and neck" to cover additional vascularized composite grafts from the head and neck needed
	Covered VCA(s)	Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	

Policy Language	Proposed Clarification		Justification
			to support transplant of the listed body parts
Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis)	**Type**	Abdominal wall	• Updated to cover "any group of" vascularized skeletal elements that need to be transplanted as part of an abdominal wall graft
	Covered VCA(s)	Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	
Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)	**Type**	Genitourinary organ	• Replaced "/" with "and" to clarify that internal and external male and female genitalia are covered VCAs under the "genitourinary organ" VCA type
	Covered VCA(s)	Uterus, internal and external male and female genitalia, and urinary bladder	
Glands (including, but not limited to adrenal or thymus)	**Type**	Vascularized gland	• Added "vascularized" in front of "gland" to emphasize that such body parts are only considered VCA transplants if they meet the criteria in the Final Rule definition of VCA
	Covered VCA(s)	Adrenal and 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)	**Type**	Lower limb	• Added "any group of vascularized body parts from the lower limb" since grafts used for lower limb transplants can vary in terms of the size of the graft and the anatomic structures included • Removed "anterior lateral thigh flaps" as they are encompassed by "any group of vascularized body parts from the lower limb"
	Covered VCA(s)	Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	
Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap)	**Type**	Musculoskeletal composite graft segment	• Replaced "any other vascularized muscle, bone, nerve, or skin flap" with "and other composite graft of vascularized muscle, bone, nerve, or skin" to clarify that composite grafts that include skin or nerve would fall under this VCA type if not covered
	Covered VCA(s)	Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	

Policy Language	Proposed Clarification		Justification
			under another VCA type (e.g. upper or lower limb) • Added "chest wall" to clarify that it falls within this category • Removed "latissimus dorsi" as it is encompassed under the language for "composite graft"
Spleen	**Type**	Spleen	• No changes
	Covered VCA(s)	Spleen	

To better identify the covered body parts in VCA-specific policies, the Committee proposes changes to subsequent policies and bylaws to clarify that the policies and bylaws apply only to "covered VCA," and to clarify the distinction between the VCA types and the body parts covered under each VCA type. This includes clarifications to implemented policy language as well as clarifications to policy language that has been approved by the Board but not yet implemented.

There is one place in which the Committee proposes referring to "VCA" rather than "covered VCA." In *Policy 5.3.B Infectious Disease Screening Criteria*, Table 5-1 Donor Infectious Disease Screening Criteria refers to the match run rather than organ type. The OPTN intends to refer to the "VCA match run" rather than the "covered VCA match run" as, by definition, only candidates registered for a covered VCA will be listed on the VCA match run.

Changes to Address Questions from the Transplant Community

To clarify that gland transplant procedures must include surgical connection of blood vessels to be considered VCA transplants, the Committee proposes adding the word "vascularized" in front of "gland" (referring to the VCA type that covers adrenal and thymus glands), "parathyroid gland," and "thyroid" in the list of covered body parts to emphasize that these body parts are only considered VCA when they meet the criteria listed in the regulatory definition of VCA. The Committee also proposes adding "chest wall" as a covered VCA under the "musculoskeletal composite graft segment" VCA type. These clarifications are included above in **Table 1**.

Other Administrative Changes

The Committee proposes additional administrative changes to policies and bylaws. First, changes to *Policy 3.6.A Waiting Time for Inactive Candidates* were approved by the Board in December 2020 as part of the briefing paper *Programming VCA Allocation in UNet*.[25] This change allows candidates registered for any VCA to accrue unlimited waiting time while inactive. With the addition of VCA to this policy, this policy now covers all organs under the purview of the OPTN by name, but the policy states that candidates registered for "all other organs" will accrue up to 30 days of waiting time while inactive. As there are no organs that would be covered by this provision for "all other organs," the Committee proposes striking it from the policy because it is superfluous.

[25] "Programming VCA Allocation in UNet," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf.

Additionally, *Policy 12.1 Waiting Time* currently states, "For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate." There are no longer any candidates registered for VCA who were registered prior to September 1, 2014. Accordingly, the Committee proposes striking this sentence from the policy.

Finally, the Committee proposes a correction to the definition of a "designated transplant program" in OPTN Bylaws to reflect that the OPTN, rather than the MPSC, approves organ-specific programs, and to remove an unnecessary word ("to") from a sentence.

Implementation

The Committee proposes implementing most of these clarifications (as outlined in **Appendix 1: Policy and Bylaws Language Effective Upon Approval**) to OPTN Policies and Bylaws immediately to support implementation of updated membership requirements for VCA transplant programs, which are defined by VCA type. Immediate implementation of these clarifications will also alleviate concerns regarding compliance with the Final Rule impacting the briefing paper *Modify Living Donation Policy to Include Living VCA Donors*[26] so that it may go forward to the Board for consideration. Separately, the Committee proposes implementing clarifications to policy language added via the approved board actions *Programming VCA Allocation in UNet*[27] and *Modify Data Collection on VCA Living Donors*[28] at a future date to coincide with OPTN implementation of those actions (as outlined in **Appendix 2: Policy Language Effective with Implementation of Programming VCA Allocation in UNet and Modify Data Collection on VCA Living Donors**).

[26] "Modify Living Donation Policy to Include Living VCA Donors," Briefing Paper, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/4199/bp_202012_modify-living-donor-policy-to-include-living-vca-donors.pdf.
[27] "Programming VCA Allocation in UNet," Policy Notice, OPTN, accessed March 16, 2021, https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf.
[28] "Modify Data Collection on VCA Living Donors," OPTN, Policy Notice, accessed April 23, 2021, https://optn.transplant.hrsa.gov/media/4248/policy-notice_vca-ld-data-collection_december-2020.pdf.

Appendix 1: Policy and Bylaws Language Effective Upon Approval

OPTN Policies

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

O

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets,* and *Policy 12: Allocation of Covered Vascularized Composite Allografts*.

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meet~~A body part meeting *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.

~~The following body parts are considered VCAs:~~

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

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.14.E Deceased Donor Authorization Requirement

The host OPO may only recover organs that it has received authorization to recover. An authorized organ should be recovered if it is transplantable or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

Recovery of covered ~~vascularized composite allografts (~~VCAs~~)~~ for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for covered VCAs must be documented by the host OPO.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the *Organ Export Verification Form* to the OPTN prior to exporting deceased donor organs.

This policy does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to covered VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to covered VCA transplants.

Policy 12: Allocation of Covered Vascularized Composite Allografts ~~(VCA)~~

12.1 Waiting Time

Waiting time for ~~VCA~~ candidates registered for a covered VCA begins when the candidate is registered on the waiting list. Candidates are registered by covered VCA type: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. ~~For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.~~

12.2 Covered VCA Allocation

A covered VCA~~s~~ from a deceased donor~~s~~ is~~are~~ allocated to candidates registered for that covered VCA ~~in need of that VCA~~ according to *Table 12-1* below.

Table 12-1: Allocation of Covered VCAs from Deceased Donors

Classification	Candidates that are registered for the covered VCA at a transplant hospital that is within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

When a covered VCA is allocated, the host OPO must document *both* of the following:

1. How the organ is allocated and the rationale for allocation.
2. Any reason for organ offer refusals.

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 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 for blood type. For covered 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. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For covered 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 known available 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 test results. If the results are conflicting or indeterminate, the recovery hospital must refer to their written protocol as outlined in *Policy 14.5.A: Living Donor Blood Type Determination*.
    c. Match the result reported to the OPTN or VCA donor medical record

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

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-2 below.*

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

	The host OPO must report *all* of the following *positive* results:	To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or covered head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures *(*bacterial or *Candida species) only* to transplant programs receiving kidneys or covered genitourinary organ VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (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, all	*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	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 covered deceased donor VCA organ that is offered to a potential covered 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
Host OPO	*Deceased donor registration* (DDR)	30 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors

The following member:	Must submit the following materials to the OPTN:	Within:	For:
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 covered VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	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)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 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 submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	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 covered 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.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 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

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN. 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. *Table 18-2: Timely Data Collection* 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

Information is timely if this Member:	Collects this information for this form:	Within this time period:
		or 42 days following the transplant date, whichever is first This does not apply to covered VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or This does not apply to covered VCA transplants.

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

This policy does not apply to covered VCA organ offers; instead, members must document covered VCA offers according to *Policy 18.1: Data Submission Requirements*.

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Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval for each designated VCA transplant program.
- Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.

There are eight types of VCA transplant programs: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, and spleen. For approval as a designated VCA transplant program, transplant hospitals must also:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. Have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in *Section J.2* above, the surgeon for an upper limb transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
   b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
   c. Acted as primary surgeon of a least 1 upper limb transplant.
   d. Participated in the post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

   The upper limb procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

   In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:
   a. Be ineligible for American board certification.
   b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
      i. Why an exception is reasonable.

ii. The surgeon's overall qualifications to act as a primary upper limb transplant surgeon.
iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.2 above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
   b. Participated in the pre-operative evaluation of at least 3 potential head and neck transplant patients.
   c. Acted as primary surgeon of a least 1 head and neck transplant.
   d. Participated in the post-operative follow-up of at least 1 head and neck recipient for 1 year post-transplant.

   The head and neck procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

   In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary head and neck transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA transplant program intending to transplant covered VCA body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. The VCA transplant program must specify the types of body parts it will transplant in the application from the following options: genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. In addition to the requirements as described in section J.2 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

~~1. Specify to the OPTN Contractor the types of VCA transplant the surgeon will perform: according to *OPTN Policy 1.2: Administrative Rules and Definitions, Vascularized Composite Allograft*.~~

~~2.~~ 1. Have current American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada certification in a specialty relevant to the type of VCA transplant the surgeon will be performing.

In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60

hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
   i. Why an exception is reasonable.
   ii. The surgeon's overall qualifications to act as a primary VCA transplant surgeon.
   iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
   iv. Any other matters judged appropriate.

   If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

~~3.~~ 2. Have performed the pre-operative evaluation of at least 3 potential covered VCA transplant patients.

~~4.~~ 3. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.

~~5.~~ 4. Have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. These procedures must be documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning that is specific for the types of VCA transplant the program will perform.

A letter from the presiding executive of the transplant hospital where the VCA transplant will be performed must provide written verification that requirements 1 through 5 above have been met by the primary surgeon

Appendix M: Definitions

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

D

Designated Transplant Program

An organ-specific program that has been approved by the OPTN~~MPSC to~~ as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, intestines, ~~and vascularized composite allografts~~ upper limbs, head and neck VCAs, abdominal walls, genitourinary organs, vascularized glands, lower limbs, musculoskeletal composite graft segments, and spleens. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meets~~A body part meeting *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

~~For the list of covered VCA body parts designated by the OPTN as VCAs, see Vascularized Composite Allograft (VCA) in OPTN *Policy 1.2: Definitions*.~~ Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.

Appendix 2: Policy Language Effective with Implementation of *Programming VCA Allocation in UNet*[29] and *Modify Data Collection on VCA Living Donors*[30]

3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
Lung and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any covered VCA	Unlimited time
~~All other organs~~	~~Up to 30 days~~

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below.

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA

[29] "Programming VCA Allocation in UNet," Policy Notice, OPTN, accessed May 3, 2021, https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf.
[30] "Modify Data Collection on VCA Living Donors," Policy Notice, OPTN, accessed May 3, 2021, https://optn.transplant.hrsa.gov/media/4248/policy-notice_vca-ld-data-collection_december-2020.pdf.

Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA

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
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, pancreas, or <u>covered</u> VCA 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, pancreas, or <u>covered</u> VCA that is offered to a potential 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
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
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to domino donor, and non-domino therapeutic donor organs.
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 • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
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

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
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, pancreas, or covered 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.
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, pancreas, or covered VCA candidate on the waiting list or recipient transplanted by the hospital

#

Policy and Bylaws Language

RESOLVED, that the changes to *Policies 1.2: Definitions, 2.14.E: Deceased Donor Authorization Requirement Policy, 12: Allocation of Vascularized Composite Allografts (VCA), Policy 12.1: Waiting Time, 12.2: VCA Allocation, 15.4.A: Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions,* as well as changes to Bylaws in *Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs* and *Appendix M: Definitions,* as set forth in Exhibit A, are hereby approved, effective June 14, 2021.

FURTHER RESOLVED, that the changes to *Policies 2.2: OPO Responsibilities, 5.4.B: Order of Allocation, 5.6.A: Receiving and Reviewing Organ Offers, 5.6.B: Time Limit for Review and Acceptance of Organ Offers*, *12.2: VCA Allocation*, *18.1: Timely Submission of Certain Data*, and *18.3: Recording and Reporting the Outcomes of Organ Offers*, as set forth in Exhibit B, are hereby approved, effective June 14, 2021 and shall expire upon the implementation of the December 2020 Board-approved proposal "Programming VCA Allocation in UNet."

FURTHER RESOLVED, that the changes to *14.5.C: Reporting of Living Donor Blood Type and Subtype, 18.1: Timely Submission of Certain Data*, and *18.2 Timely Collection of Data*, as set forth in Exhibit C, are hereby approved, effective June 14, 2021, and shall expire upon the implementation of the December 2020 Board-approved proposal "Modify Data Collection on VCA Living Donors."

FURTHER RESOLVED, that the changes to *Policies 3.6.A: Waiting Time for Inactive Candidates, 5.3.B: Infectious Disease Screening Criteria,* and *18.1.B: Timely Submission of Certain Data,* as set forth in Exhibit D, are hereby approved, effective pending implementation and notice to OPTN members.

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.

Exhibit A

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb

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

O

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets,* and *Policy 12: Allocation of Covered Vascularized Composite Allografts*.

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meet~~A body part meeting *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.

9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.

~~The following body parts are considered VCAs:~~

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

2.14.E Deceased Donor Authorization Requirement

The host OPO may only recover organs that it has received authorization to recover. An authorized organ should be recovered if it is transplantable or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

Recovery of covered ~~vascularized composite allografts (~~VCAs~~)~~ for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for covered VCAs must be documented by the host OPO.

Policy 12:Allocation of Covered Vascularized Composite Allografts ~~(VCA)~~

12.1 Waiting Time

Waiting time for ~~VCA~~ candidates registered for a covered VCA begins when the candidate is registered on the waiting list. Candidates are registered by covered VCA type: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. ~~For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.~~

12.2 Covered VCA Allocation

A covered VCA~~s~~ from a deceased donor~~s~~ is~~are~~ allocated to candidates registered for that covered VCA ~~in need of that VCA~~ according to *Table 12-1* below.

Table 12-1: Allocation of Covered VCAs from Deceased Donors

Classification	Candidates that are registered for the covered VCA at a transplant hospital that is within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

When a VCA is allocated, the host OPO must document *both* of the following:

1. How the organ is allocated and the rationale for allocation.
2. Any reason for organ offer refusals.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-2 below.*

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

	The host OPO must report *all* of the following *positive* results:	To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or covered head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures *(*bacterial or *Candida species) only* to transplant programs receiving kidneys or covered genitourinary organ VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	3. The receiving transplant program's patient safety contact 4. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

OPTN Bylaws

Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval for each designated VCA transplant program.
- Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.

There are eight types of VCA transplant programs: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, and spleen. For approval as a designated VCA transplant program, transplant hospitals must also:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. Have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in *Section J.2* above, the surgeon for an upper limb transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
   b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
   c. Acted as primary surgeon of a least 1 upper limb transplant.
   d. Participated in the post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

   The upper limb procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that

can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary upper limb transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.2 above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.

b. Participated in the pre-operative evaluation of at least 3 potential head and neck transplant patients.
c. Acted as primary surgeon of a least 1 head and neck transplant.
d. Participated in the post-operative follow-up of at least 1 head and neck recipient for 1 year post-transplant.

The head and neck procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary head and neck transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA transplant program intending to transplant covered VCA body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. The VCA transplant program must specify the types of body parts it will transplant in the application from the following options: genitourinary organ,

vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. In addition to the requirements as described in section J.2 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

~~1. Specify to the OPTN Contractor the types of VCA transplant the surgeon will perform: according to *OPTN Policy 1.2: Administrative Rules and Definitions, Vascularized Composite Allograft*.~~

~~2.~~ 1. Have current American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada certification in a specialty relevant to the type of VCA transplant the surgeon will be performing.

In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary VCA transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

~~3.~~ 2. Have performed the pre-operative evaluation of at least 3 potential covered VCA transplant patients.

~~4.~~ 3. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.

~~5.~~ 4. Have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. These procedures must be

documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning that is specific for the types of VCA transplant the program will perform.

A letter from the presiding executive of the transplant hospital where the VCA transplant will be performed must provide written verification that requirements 1 through 5 above have been met by the primary surgeon

Appendix M: Definitions

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

D

Designated Transplant Program

An organ-specific program that has been approved by the OPTN~~MPSC to~~ as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, intestines, ~~and vascularized composite allografts~~ upper limbs, head and neck VCAs, abdominal walls, genitourinary organs, vascularized glands, lower limbs, musculoskeletal composite graft segments, and spleens. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meets~~A body part meeting *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

~~For the list of covered VCA body parts designated by the OPTN as VCAs, see Vascularized Composite Allograft (VCA) in OPTN *Policy 1.2: Definitions*.~~ Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.

#

Exhibit B

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.

2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to Policy 16.6.A: Extra Vessels Use and Sharing.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the Organ Export Verification Form to the OPTN prior to exporting deceased donor organs.

This policy does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to covered VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to covered VCA transplants.

12.2 VCA Allocation

VCAs from deceased donors are allocated to candidates in need of that VCA according to *Table 12-1* below.

Table 12-1: Allocation of VCAs from Deceased Donors

Classification	Candidates that are registered at a transplant hospital that is at or within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

Within each classification, candidates are sorted by waiting time (longest to shortest).

When a covered VCA is allocated, the host OPO must document *both* of the following:

1. How the organ is allocated and the rationale for allocation.
2. Any reason for organ offer refusals.

18.1.B Timely Submission of Certain Data

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

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (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, all	*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	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 covered deceased donor VCA organ that is offered to a potential covered 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
Host OPO	*Deceased donor registration* (DDR)	30 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

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	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)	60 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)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 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 submits the *recipient feedback* form	Each liver recipient transplanted by the hospital

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Transplant hospitals	*Recipient feedback*	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 covered 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.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 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

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

This policy does not apply to covered VCA organ offers; instead, members must document covered VCA offers according to *Policy 18.1: Data Submission Requirements*.

Exhibit C

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 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 for blood type. For covered 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. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For covered 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 known available 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 test results. If the results are conflicting or indeterminate, the recovery hospital must refer to their written protocol as outlined in *Policy 14.5.A: Living Donor Blood Type Determination*.
   c. Match the result reported to the OPTN 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.B Timely Submission of Certain Data

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

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
OPOs, all	*Death notification records* (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, all	*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	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
Host OPO	*Deceased donor registration* (DDR)	30 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 covered VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	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

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 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 submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	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

The following member:	*Must submit the following materials to the OPTN:*	*Within:*	*For:*
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.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 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

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN. 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. *Table 18-2: Timely Data Collection* 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 covered VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or This does not apply to covered VCA transplants.

Exhibit D

3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
Lung and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any covered VCA	Unlimited time
~~All other organs~~	~~Up to 30 days~~

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below.

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA
Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, ~~any~~ VCA

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
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, pancreas, or covered VCA 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, pancreas, or covered VCA that is offered to a potential 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
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

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
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
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to domino donor, and non-domino therapeutic donor organs.
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 • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
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, pancreas, or covered VCA recipient

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
			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.
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, pancreas, or covered VCA candidate on the waiting list or recipient transplanted by the hospital

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