

At-a-Glance

Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)

- **Affected/Proposed Policies and Bylaws**

Policy 1.2 Definitions; 2.2 OPO Responsibilities; 2.12.C Authorization Requirement; 5.2 Maximum Mismatched Antigens; 5.4.B Order of Allocation; 5.5.A Receiving and Reviewing Organ Offers; 5.5.B Time Limit for Acceptance; 5.9 Allocation of Other Organs (Elimination); 12.1 Waiting Time; 12.2 VCA Allocation; 14.6 Registration and Blood Type Verification of Living Donors before Donation; 18.1 Data Submission Requirements; 18.2 Timely Collection of Data; 18.3 Recording and Reporting the Outcomes of Organ Offers; OPTN Bylaws, Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs; Appendix D.2 Designated Transplant Program Requirement; OPTN Bylaws, Appendix J Membership Requirements for Vascularized Composite (VCA) Transplant Programs; Appendix K Transplant Program Inactivity, Withdrawal, and Termination; Appendix M Definitions

- **Vascularized Composite Allograft (VCA) Transplantation Committee**

This proposal updates existing OPTN policy and bylaw language and establishes new requirements to add Vascularized Composite Allografts (VCAs) to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). Specifically, it contains the following elements:

1. Definition of a VCA
2. VCA Membership Criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

In February, 2014, all U.S. OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal meets five of the six goals outlined in the OPTN Strategic Plan:

Goal 1: Increase the number of transplants

Goal 2: Increase access to transplants

Goal 3: Improve survival for patients

Goal 4: Promote transplant patient safety

Goal 6: Promote the efficient management of the OPTN

Establishing a system for VCA transplantation addresses the key goals outlined above by:

- Providing consistency and structure to VCA policies and programs.
- Improving access to VCA transplantation for patients who might benefit by clarifying VCA donor authorization and related protocols.
- Facilitating the development and exchange of information about candidate appropriateness for transplant, available VCA donors and candidates, and candidate prioritization.
- Helping to maximize the number of VCAs recovered for transplant and promote the best use of donated organs.
- Developing guidance for the evaluation and management of VCA candidates.
- Addressing the changing field of transplantation by responding to a new area of organ allocation policy development.

Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)

Affected/Proposed Policy:

OPTN Policy 1.2 Definitions; 2.2 OPO Responsibilities; 2.12.C Authorization Requirement; 5.2 Maximum Mismatched Antigens; 5.4.B Order of Allocation; 5.5.A Receiving and Reviewing Organ Offers; 5.5.B Time Limit for Acceptance; 5.9 Allocation of Other Organs (Elimination); 12.1 Waiting Time; 12.2 VCA Allocation; 14.6 Registration and Blood Type Verification of Living Donors before Donation; 18.1 Data Submission Requirements; 18.2 Timely Collection of Data; 18.3 Recording and Reporting the Outcomes of Organ Offers; Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs; Appendix D.2 Designated Transplant Program Requirement; Appendix J Membership Requirements for Vascularized Composite (VCA) Transplant Programs; Appendix K Transplant Program Inactivity, Withdrawal, and Termination; Appendix M Definitions

Vascularized Composite Allograft (VCA) Transplantation Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

This proposal updates existing OPTN policy and bylaw language and establishes new requirements to add Vascularized Composite Allografts (VCAs) to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). Specifically, it contains the following elements:

1. Definition of a VCA
2. VCA Membership Criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

By statute, the Secretary of HHS may expand the definition of human organs and has exercised this authority by adding VCAs to the covered list of human organs under the OPTN modified Final Rule. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop VCA policies prior to implementation of the modified Final Rule which became effective July 3, 2014. *Because of the pending statutory change at the time, these policy changes were approved by the OPTN Board of Directors during its June 23-24, 2014 meeting with a "sunset" date on September 1, 2015. The Board will review and consider these public comments for approval during the June 1-2, 2015 meeting.* More discussion within the VCA transplant community will be necessary to develop a refined system guiding OPTN, OPO, and transplant center processes for VCA transplantation.

The Bylaws and Policies contained within this proposals mirror those approved by the Board in June 2014. Concurrent with that effort, the VCA Committee began work on more long-term, substantive data collection policies. A separate proposal concerning those efforts is also being released during this public comment period. If comment is favorable on the separate data collection proposal, those provisions would be forwarded for final approval instead of the proposed amendments to Policies 18.1 and 18.2 in this proposal.

Background and Significance of the Proposal:

Vascularized Composite Allotransplantation i.e. “allografts” (VCA) refers to transplants composed of several different kinds of tissues (i.e., skin, muscle, bone), such as those in the hand, arm, or face, transferred from donor to recipient as a single functional unit.¹ This emerging field of transplantation has become a viable reconstructive option for patients with extensive tissue defects and severe dysfunction, often achieving functional and cosmetic outcomes not previously possible with existing techniques. Over the past decade, a rapidly growing number of face and upper extremity transplants have been performed worldwide with highly encouraging outcomes.² A number of OPTN member transplant hospitals are currently performing these types of procedures, necessitating oversight of this new area of transplantation.

On March 3, 2008, HRSA, a division of the Department of Health and Human Services (HHS), published a Request for Information (RFI) in the Federal Register requesting feedback from stakeholders and the public on whether VCAs should be included within the OPTN Final Rule's definition of organs. The RFI also sought input on whether VCAs should be added to the definition of human organs covered by section 301 of NOTA.

Based upon a review of VCA characteristics and submitted public comments, it was determined that VCAs should be included within the definition of organs covered by the OPTN Final Rule (42 CFR part 121) and section 301 of NOTA. On December 16, 2011, this intention was published in a notice of proposed rulemaking in the Federal Register. The addition of VCAs to the OPTN Final Rule's definition of organs, subjects VCA transplantation to the requirements of the OPTN Final Rule and OPTN oversight.

The OPTN was subsequently directed by HRSA to establish policies regarding VCA transplantation within its existing policy structure, with the goal of instituting a basic framework for VCA transplantation prior to implementation of the Final Rule modifications on July 3, 2014. Because of the pending statutory change at the time, these policy changes were approved by the OPTN Board of Directors during its June 23-24, 2014 meeting with a “sunset” date on September 1, 2015.

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (Committee), comprising representation from U.S. transplant programs with experience in VCA transplantation and the major transplant and procurement societies, discussed and proposed policy and bylaw recommendations for the major areas identified for VCA program and allocation oversight. The Committee and subcommittees reviewed and discussed internal processes of transplant programs currently involved in VCA transplants. The Committee also examined the evolving body of literature surrounding VCA transplantation, to define the major issues involved with creating a temporary but workable structure for VCA programs.

¹ Blake D. Murphy, Ronald M. Zuker, Gregory H. Borschel, “Vascularized composite allotransplantation: An update on medical and surgical progress and remaining challenges,” *Journal of Plastic, Reconstructive, and Aesthetic Surgeons*, 66, no.11 (2013): 1449 <http://www.ncbi.nlm.nih.gov/pubmed/23867239>.

² Gerald Brandacher, “Composite tissue transplantation”, *Methods Mol Biol.* (2013); 1034: 103. doi: 10.1007/978-1-62703-493-7_5

A review of available literature shows that professional experience in VCA transplantation is progressing, with close to 150 procedures performed worldwide.³ Outstanding results of more than a decade have been achieved with excellent short and long-term outcomes reported. Although functional outcomes have exceeded expectations, acute rejections are common in the early postoperative period with immunosuppression related side-effects often reported.⁴ The risks of lifelong immunosuppression continue to be an important factor when evaluated against quality of life and functional benefits. OPTN oversight of this developing field will help provide the framework for an effective and balanced system, facilitating the collection of data for studying outcomes and best practices, and maximizing the benefit to patients and society.⁵

In preparation for VCA policy development efforts, the VCA Committee viewed the results of a survey of the Association of Organ Procurement Organizations (AOPO) to assess the number of hospitals currently transplanting VCAs, or planning to in the near future. The number of transplant programs involved in VCA transplantation is small, though interest in VCA transplantation is increasing. As of February 2014, the results of the survey showed:

- 28 VCA transplant recipients were transplanted at 11 different transplant centers.
 - 6 face transplants
 - 7 bilateral upper extremities
 - 14 unilateral upper extremities
 - 1 multiple VCA transplant – a face and a bilateral upper extremity.
- 9 patients at 6 different transplant centers were waiting for a VCA transplant
 - 4 awaiting a face transplant
 - 4 awaiting a bilateral upper extremity transplant
 - 1 awaiting a unilateral upper extremity transplant.

There are an additional nine transplant hospitals in the planning stages for a new VCA transplant program, with a few close to approving patients, including one children's hospital.

Although the VCA field is emergent and literature examining outcomes is still evolving, incorporation of these procedures within the authority of NOTA and the Final Rule is evidence of its significance to the field of transplantation. More data is needed to investigate immunologic issues and characteristics of VCA unique to face vs. hand transplantation. As the field advances, this additional evidence will help guide future policy decisions.

³ Diaz-Siso JR, Bueno EM, Sisk GC, Marty FM, Pomahac B, Tullius SG. "Vascularized composite tissue allotransplantation--state of the art", *Clin Transplant*. (2013) May-Jun; 27(3): 330. Epub 2013 Apr 14.

⁴ Kaufman CL, Ouseph R, Marvin MR, Manon-Matos Y, Blair B, Kutz JE.. "Monitoring and long-term outcomes in vascularized composite allotransplantation," *Curr Opin Organ Transplan*. (2013): 652, <http://www.ncbi.nlm.nih.gov/pubmed/24220047>

⁵ Cendales, LC, Rahmel, A, Pruett, TL, "Allocation of vascularized composite allografts: what is it?" *Transplantation*, (2012): 1086. doi: 10.1097/TP.0b013e31824b073f.

Supporting Evidence and/or Modeling:

This proposal establishes minimum requirements for OPTN transplant programs that perform VCA transplantation. Specifically, it contains the following elements:

1. Definition of a VCA
2. VCA Membership Criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

Definition of a VCA

The final rule modifications require the OPTN to “identify all covered body parts in any policies specific to vascularized composite allografts, defined in §121.2,⁶” so that VCAs are able to be clearly distinguished as organs under the OPTN policy framework. On February 25, 2014, the VCA Committee convened in Chicago Illinois to discuss VCA topics, including a definition of covered VCA parts. The VCA Committee first needed to confirm that VCAs were covered under the purview of HRSA under the final rule and not the Food and Drug Administration (FDA), as the definition of a VCA contains components previously regulated by the FDA. Based upon their clinical characteristics, the HHS has determined that VCAs are more characteristic of organs as defined specifically in NOTA and subject to regulation consistent with organ transplantation. The Committee discussed distinguishing factors between cellular and tissue-based products regulated by the FDA and those components under the purview of the OPTN, since a body part would be excluded from the coverage of FDA regulations once it is defined as an organ under the OPTN final rule. The OPTN modified final rule includes nine criteria that must be met in entirety for a body part to be defined as a VCA.

The nine criteria for VCAs are:

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

The Committee reviewed and discussed the nine criteria. An initial concern was expressed with regard to criterion 7 which refers to “a device” that in combination with another article would change its classification as a VCA organ. No specific examples were recognized that would

⁶ OPTN Final Rule 42 CFR 121.2 - Definitions

pertain to face and limb transplants; however, the Committee discussed the possibility of future advancements in technology and medicine that could eventually incorporate a mechanical device within a composite, causing a change in its definition. The Committee requested that HRSA contact the FDA to obtain clarity on criterion #7.

The Committee also discussed other body parts that could be incorporated into the definition of a VCA transplant in the future. Upper extremity (most notably hands) and face transplants are the most frequently performed VCA transplant procedures in the U.S. and are the subject of extensive ongoing clinical research programs. Under the modified final rule, any OPTN policy that applies broadly to solid organs would apply to all body parts meeting the definition for VCAs unless otherwise specified. Therefore, other VCA procedures meeting the nine criteria to define a body part as a VCA, would also be subject to general OPTN policies. See Fig 1 below.

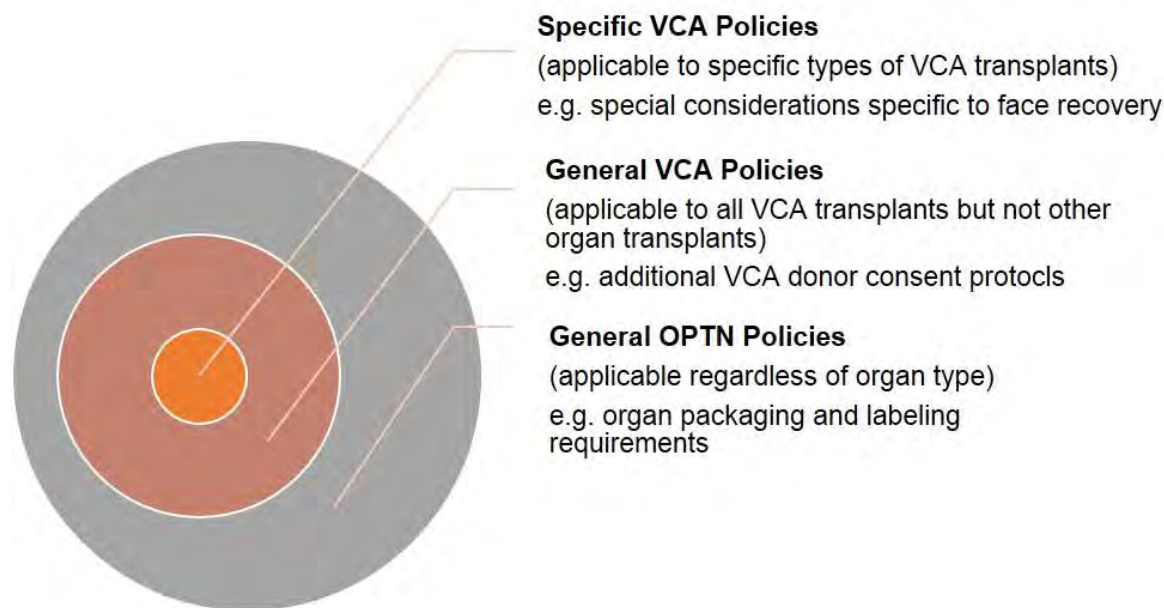


Figure 1: Tiers of OPTN Policy as applicable to VCA transplants.

For the initial phase of policy development, OPTN VCA policies will focus on upper extremity and face transplants. As the field advances, specific body parts may be added to the list of VCA organs with subsequent development of new policies.

During its conference call meeting on March 25, 2014, the VCA Committee was updated with the requested clarification from HRSA regarding criterion 7. The Committee was advised that the FDA would determine if there has been a material change to the device which could impact the safety, effectiveness, purpose, or use of that device. As long as the VCA and any devices used during the procedure are not changed for an unintended purpose, the transplant would remain under the oversight of the OPTN. As the concerns raised by criterion 7 seemed to be outside of the intention of adding the nine criteria to the OPTN final rule, the Committee confirmed its intent to adopt the nine criteria as written, with public comment feedback offering the potential for more interpretive, clarifying language in the future.

During its March 29, 2014 meeting, the Committee unanimously supported (16 approve, 0 oppose, 0 abstain) a motion to submit the proposed OPTN policy language for the Board of Director's consideration at its June 23-24, 2014 meeting. No further changes were made to the approved policy language during subsequent committee or Board discussions.

Final approved policy language is included at the end of this proposal.

VCA Membership Criteria

As the OPTN Contractor, UNOS is a membership organization which is required under NOTA to establish membership and medical criteria for allocating organs. The OPTN Bylaws contain numerous membership requirements that must be in place at the transplant hospital, and approved by the Membership and Professional Standards Committee (MPSC), before the hospital may be involved with transplantation. As such, basic bylaw language would need to be in place to accommodate OPTN membership for VCA programs in preparation for the July 3, 2014 modified final rule implementation date. Future VCA membership bylaws will address care, provider, and infrastructure requirements.

During its meeting on February 25, 2014, the VCA Committee reviewed draft bylaw language and a list of necessary elements for a VCA program prepared by the American Society of Transplant Surgeons (ASTS) VCA Committee, to establish the basic membership requirements for VCA programs that will be sent for the Board's consideration in June.⁷ The limited number of VCA transplants performed to date prevented comparison of current membership requirements for other organ-specific programs against VCA membership requirements. Therefore, the Committee was cautioned against developing overly specific language for personnel for whom no requirements or comparison currently exists. The Committee discussed core membership requirements for VCA programs. A reconstructive surgical director and medical director were suggested as identified responsible VCA program staff in an attempt to simulate the primary surgeon/surgical director and primary physician/medical director bylaw structure. The Committee also supported the use of a letter template referenced in the proposed bylaws language that would obtain all necessary VCA transplant program information in place of a formal membership application.

The required timing for member notification to the OPTN of its intention to perform VCA transplants was discussed. The Committee considered including the time that a potential VCA recipient is identified and the time a candidate is considered "listed," but ultimately decided against both because adding VCA candidates to a waiting list on UNetSM will not be immediately feasible. The Committee determined that other preparations, including preliminary screening of patients, were more indicative of program intent, and added language requiring that a transplant hospital notify the OPTN Contractor once it has patients "ready to undergo screening for a VCA transplant." The requirement for a VCA program to be at a transplant hospital that is a "member in good standing" was also added, as well as a recommendation to require a letter from the program's local OPO, attesting to its interaction with the potential VCA program about the necessary coordination of logistics, etc. of establishing a program. Requiring this exchange with the local OPO would demonstrate that a program has begun the necessary planning to perform VCA transplants.

⁷ Cendales, L., Granger, D., Henry, M., Jones, J., Langnas, A., Levi, D., Magee, J., Merion, R., Olthoff, K., Pruett, T., Roberts, J. and Abecassis, M., "Implementation of Vascularized Composite Allografts in the United States: Recommendations From the ASTS VCA Ad Hoc Committee and the Executive Committee", *American Journal of Transplantation*, (2011) 11: 13–17. doi: 10.1111/j.1600-6143.2010.03374.x

Following review of the initial requirements, the Committee unanimously supported the draft language and recommended that a VCA Membership Subcommittee be created to review the draft language for additional core membership requirements.

On March 25, 2014, the VCA Membership Subcommittee met by teleconference call to discuss additional edits to the bylaw language suggested by UNOS staff. The edits included eliminating the requirement that the program be a “member in good standing” and presentation of two options for clarifying whether the VCA transplant hospital must have another approved transplant program in operation to *receive and maintain* VCA transplant program approval. UNOS staff noted that the terms “member in good standing” and “member not in good standing” are not defined in the OPTN/UNOS Bylaws and the process to define these terms would require additional input from numerous stakeholders, which would be outside of the scope of the VCA membership requirements. The subcommittee also discussed whether the VCA program would be able to maintain program approval if the approved transplant program were to close. Committee members expressed that the transplant hospital must have another functioning transplant program, since the VCA program would rely on that program’s transplant expertise. Additionally, it would be advantageous for new VCA programs to align with the organization and structure required of OPTN approved transplant hospitals. The Committee agreed to amend the bylaw language removing the term “member in good standing and adding language requiring a hospital to have another approved transplant program in addition to the VCA program, in order to receive and maintain VCA transplant program approval.

The subcommittee also discussed the recommendation for the transplant hospital to contact the OPTN about the establishment of a VCA program when it “has a candidate ready to undergo screening for a VCA transplant.” UNOS staff expressed concern that the language was not well defined for compliance monitoring purposes. The Committee recommended modifying the language to state that a transplant hospital must contact the OPTN upon its commitment to perform VCA transplants. The Committee unanimously supported the amended bylaw language.

On April 22, 2014, the VCA Membership Subcommittee met again to determine if additional requirements should be added to the proposed bylaws. The subcommittee agreed that three positions (chief administrative office for the institution, a reconstructive surgeon, and a transplant specialist), all with specific named expertise, should be designated as responsible VCA transplant program personnel and required to sign the letter of intent which would serve as the application for a VCA program.

During its conference call on April 29, 2014, the VCA Committee approved additional bylaw language recommended by UNOS staff, specifying that the letter of notification also include the contact information and signatures of each of the three named VCA program personnel.

The Committee approved (For – 11, Against – 0, Abstention – 0) the amended bylaw language detailing basic Membership Requirements for VCA Transplant Program, for the Board of Director’s consideration at its June 2014 meeting. An amendment to the proposed bylaw language was made at the Board meeting to correct discrepant language that appeared in the Board book.

Final approved bylaw language included at the end of this proposal.

Subsequent to the Board meeting, Committee leadership discussed and agreed that the proposal should not give a transplant hospital “blanket” approval to perform transplants of any VCA graft. The language was drafted to avoid burdensome restrictions on those VCA programs that were operating at the time of the Final Rule amendment. Future membership requirements will outline

criteria for VCA-specific transplant programs (upper limb, face, abdominal wall, etc...). A subcommittee of the VCA Committee has begun work on this effort.

VCA Allocation

Leading into the June, 2014 Board meeting were two efforts related to VCA Allocation:

- Elimination of Policy 5.9 (Allocation of Other Organs)
- Creation of a new policy regarding VCA allocation

OPTN Policy 5.9 (Allocation of Other Organs) addresses the “allocation of other organs not specifically addressed in other policies.” Prior to June 2014, the allocation of all organs were addressed in policy but when the OPTN began oversight of VCA transplants on July 3, 2014, there would have been an opportunity for confusion if OPOs tried to allocate organs using this outdated policy. This policy is outdated and contains a point system for medical urgency and distance from the transplant center that has never been programmed. Therefore, the OPO Committee voted unanimously to rescind this policy and submit the recommendation to the Board of Directors during its June 22-23, 2014 meeting. The Board agreed to eliminate Policy 5.9.

The VCA Committee was asked to develop a temporary mechanism for allocation of VCAs in preparation for implementation of the OPTN modified Final Rule. The temporary mechanism will remain in place until the Committee can develop a more robust allocation scheme that will be programmed. During its teleconference call on March 25th, the VCA Committee initially considered referencing ongoing VCA allocation policy development as an intermediate solution, to avoid unintended consequences resulting from an overly simplified policy, and allow more thorough deliberation of allocation concepts. As the VCA community is anxiously awaiting direction from the OPTN on allocation, it was determined that this guidance was needed prior to implementation of the modified Final Rule, to assist transplant programs in their decision making. The general principles of allocation outlined in NOTA and approved by the Board were used to help guide VCA allocation decisions.

The VCA Committee discussed factors that could be considered in a simple allocation policy for VCA organs, to help define candidate priority when multiple recipients are waiting and clinically eligible for a transplant. Currently, the small number of VCA patients waiting at transplant programs allows for individualized allocation arrangements with OPOs. Eventually, as program participation is expanded, rank ordering candidates with similar characteristics will require a more consistent, defensible, and methodical approach. Waiting time within the organ procurement organization’s donation service area was suggested. Although basic, it prevents the perception of unfair organ allocation and would be a reasonable first step until more refined allocation policies can be developed. The Committee recommended that a working group of VCA Committee members develop draft policy language based on allocation practices used by existing VCA programs, for presentation to the Committee during its next teleconference call.

The VCA Committee met on May 9, 2014, to review several options for a general allocation scheme for VCA transplantation. The backdrop for the effort included the stated allocation principle of increasing access of recipients to suitable donors, while safely and appropriately promoting experience in the field. As the current setting for VCA transplantation is starkly contrasted with that of traditional solid organ transplantation where organ demand exceeds supply, the goal would be to prevent the exclusion of suitable donors, due to policy requirements that are overly restrictive.

The VCA Committee viewed draft policy language presenting three options for allocating VCAs, each with a proposed definition of waiting time. It was noted generally that the use of waiting time

as a basic determinant of allocation priority, is controversial and considered to be inequitable in deceased donor allocation. If used for VCA allocation, impacts to candidates should be carefully studied. The Committee discussed revisions to the waiting time language. The Committee wanted a method to sort candidates who will have been waiting for a VCA transplant when the Final Rule amendment and OPTN oversight goes into effect. The Committee also deliberated between language indicating that waiting time will begin when an OPO actively seeks a donor for either an identified potential VCA “recipient” or “candidate.” It was noted that a “recipient” and “candidate” are defined in OPTN policy as a patient who has already received a transplant or a patient who is currently on the OPTN waiting list. Members articulated that the term “candidate” establishes that the patient has not yet been transplanted and agreed that it was the most appropriate term. The draft policy language was amended to reflect that waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

The proposed allocation options were summarized and discussed. The first option would allocate VCAs by compatible blood types and physical characteristics, distinguishing allocation of limbs by bilateral or unilateral transplants, then prioritizing according to level of HLA mismatch and candidate sensitization. The second option would allocate VCAs to candidates with compatible blood types and similar physical characteristics, prioritizing according to geography with allocation first to regional and then national candidates. The third option would allocate VCAs according to geography and level of HLA mismatch with the donor, prioritizing first local ABO identical and compatible candidates, then regional ABO identical and compatible candidates, followed by national ABO identical and compatible candidates.

The Committee debated the appropriateness of allocating VCAs based upon the underlying allocation concepts represented by the options, including degree of HLA mismatch, candidate sensitization, geography, and type/number of VCA procedures. Ethically, prioritization for a scarce resource should allow identical transplants to precede compatible transplants. However, as organ scarcity may not be established within the interim policy timeframe, prioritization based on broad HLA compatibility would be supported if impacts on blood type O recipients are carefully monitored. Additionally, prioritizing zero mismatched candidates under an interim policy could be burdensome to transplant programs and would likely only apply under very rare circumstances. Prioritization based upon candidate sensitization could be helpful for some patients, but data supporting a specific sensitization threshold for patients is currently unavailable.

In discussions regarding the use of geographic boundaries for prioritization, members delivered strong ethical arguments against the practice of using OPO boundaries as the first layer of allocation or using historical, regional boundaries, suggesting that these approaches are reliant on an outdated allocation model. The Committee also referenced the lack of data on the amount of cold ischemic time that would negatively impact VCAs. However, members agreed that if geography is used in VCA allocation, regional distribution would be the most acceptable of the methods that could be implemented in July, noting that many transplant programs will not have an active VCA program during the interim policy period.

Finally, the Committee considered candidate prioritization based upon VCA type, functionality, and number of procedures needed by a candidate. Various objectives were deliberated, including the need for two upper extremity procedures as compared to one, avoiding multiple surgeries, and matching candidate and donor characteristics. Ultimately, the Committee chose not to give priority to candidates based on the type or number of VCAs required.

Acknowledging the numerous complexities involved with determining individual candidate priority for VCAs, and recognizing that benefits from a temporary may not be demonstrated during the

interim policy period, the VCA Committee ultimately chose an option that provided the most broadly defined allocation. The option selected would allow decisions to be individualized for matching an organ to a specific patient, with processes operationalized by the transplant program. The option also circumvents application of concepts used in solid organ transplantation to VCA transplantation, when they may not be the best fit.

Because this system will not be programmed in UNetSM during the interim policy period, the manual VCA matching process was loosely outlined for the Committee:

- Transplant programs will register their VCA candidates in a document that they will securely transmit to UNOS.
- UNOS will compile all of the candidate registrations into a master list which would be distributed to OPOs.
- OPOs will match VCA donors to candidates using the master list.
- In the event an OPO identifies a VCA donor that is suitable for more than one candidate from the master list, allocation will first be offered to regional candidates.
- If the organ is not accepted regionally, allocation will be offered to national candidates.
- Within each classification, waiting time will be used as the tie breaker between candidates.

The VCA Committee approved the proposed policy language regarding VCA Allocation for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (Yes – 14, No – 0, Abstentions – 0).

Final approved policy language is included at the end of this briefing paper.

While not directly related to VCA allocation, it is worth noting that the Secretary of Health and Human Services responded to the possibility of a living VCA donor in the amendment to the OPTN Final Rule. The Secretary affirmed that oversight of living donors was under the auspices of the OPTN. The definition of a VCA in both the OPTN Policies and Bylaws was adopted from the Final Rule. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe⁸, however there are no candidates for living VCA donors registered with the OPTN. The Committee felt it was prudent to not set restrictive policy language in this evolving clinical area. As the field of VCA transplantation evolves, the VCA and Living Donor Committees will review the implications of living donation in the context of VCA. This may translate into guidance or policy language.

Authorization Requirements for VCA Donation

During its February 25th meeting, the VCA Committee reviewed draft policy language to discuss the necessary elements that should be included in a VCA donor authorization process. Addressing public comment concerns, the Committee debated whether OPOs would need to obtain authorization to recover VCAs separately from the authorization to recover other organs for transplant. As a general rule, each OPO that is currently recovering VCAs has developed separate deceased donor authorization forms for potential VCA donors that extends beyond the traditional authorization processes for potential whole organ donors. Separate authorization is necessary to maintain public trust and transparency with regard to this sensitive subject.

⁸ Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. "The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome", *American Journal of Transplantation*, (2014): 44, <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf>

There was strong support among the Committee that OPTN policy should address potential concerns from the public about individuals who have previously registered to be organ donors but likely did not consider the possibility of VCAs. Authorization to recover organs is typically governed by state law following the Uniform Anatomical Gift Act (UAGA). Although state law dictates donor authorization, the OPTN is responsible for maintaining public trust in the nation's organ allocation system. A separate VCA donor authorization policy would not necessarily conflict with state law and the language may help states develop regulations specific to VCA donor authorization. The Committee agreed that distinguishing VCA authorization in policy would be important to establish public trust and not hinder life-saving organ transplantation. After debating specific terminology that would capture the expressed concerns, the Committee suggested adding the word "distinctly" to the proposed bylaws language. In the future, once VCA transplantation is more common, the Committee will consider whether that separate authorization is still necessary. The Committee agreed that the proposed policy language addressed potential concerns from the public by sending a message that VCAs will not be recovered unless agreed to by the persons responsible for making the donation decision and voted to support the proposed draft language.

During its April 29th conference call, the VCA Committee considered additional changes to the proposed policy language on VCA authorization approved during the February 25th meeting. The proposed changes were recommended by the chair of the Ethics Committee to be consistent with state law and clarify how VCA authorization is obtained. The language proposed by the Committee appeared to only allow surrogate consent for VCA donation in the setting of legally valid donor wishes. However, this requirement is in conflict with state gift law and many donor registries, as well as the UAGA. The majority of authorization for deceased donation is obtained from a general intent registry such as the Department of Motor Vehicles (DMV) driver license renewals, which does not distinguish between organs, tissue, or VCA. Authorization for VCA is not applicable to a general intent registry, since the donor's intent to donate VCA organs is not assumed. However, under the UAGA, authorization for a general deceased donation gift would not limit authorization for an additional specific VCA gift. Therefore, authorization for the specific VCA gift can originate from *either* the donor himself or a (surrogate) donation decision maker after the donor's death.

As policy language is not intended to include prescriptive elements of the donor consent process, the Committee also identified the need to reinforce the concept of separate consent with appropriate support and educational materials that would be non-binding to members. This guidance on VCA authorization was provided to the Board as supporting materials. Several committees and interested organizations are currently reviewing the guidance. If their reviews are favorable, it will be submitted as a guidance document to the OPTN Board of Directors.

The Committee agreed that the amended language promotes consistency with the law and current donor registries, and preserved the Committee's intent for a separate consent form and conversation about VCA donation.

The Committee approved the amended policy language detailing Authorization Requirements for VCA Donation for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (For – 11, Against – 0, Abstention – 1)

Final approved policy language included at the end of this briefing paper.

Other Policy and Bylaw Modifications Specifically Exempting VCAs

In preparation for implementation of the modified Final Rule, UNOS staff researched requirements necessary for operationalizing VCA policies within the OPTN. The investigation included a comprehensive review of OPTN policies and bylaws and related UNetSM computer systems. It was determined that there were numerous sections of OPTN policy and the bylaws that would need to be amended to prevent application to VCAs and several computer systems that would need to be updated. Many OPTN/UNOS policies are not organ specific and would apply to VCAs unless specifically exempted. Additionally, several OPTN/UNOS computer systems are organ specific and would require programming updates to incorporate VCA policies. Although efforts are underway within UNOS to update these systems, the changes would not be in place by July. Therefore, electronic workaround solutions were developed to facilitate the interim policy and boilerplate policy language was proposed for specific sections of OPTN policy and the bylaws to ensure that all of the policies applicable to VCAs could be implemented and that existing safeguards for solid organs could be preserved. The proposed changes were approved by the Board in June 23-24, and will expire as solutions can be implemented.

The VCA Committee approved without edits, all proposed changes to several OPTN policies and bylaws that would be affected by addition of OPTN Policy 12.0, Vascularized Composite Allografts for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (Yes – 14, No – 0, Abstentions – 0).

Final approved policy and bylaw language is included at the end of this briefing paper.

Expected Impact on Living Donors or Living Donation:

Portions of this proposal apply to living donors and portions of this policy are specific to deceased donation.

Definition of Organ

The change of the definition of organ in the Final Rule was not specific to deceased or living donation; it therefore applies to both deceased and living donation. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe⁹; however, there are no candidates for living VCA donors registered with the OPTN at this time. The application of this change to living donation was specifically addressed in the supplementary information to the Final Rule amendment.¹⁰

Comment: One commenter questions how the VCA transplant waiting list will be categorized (i.e., by gender or race) and whether the OPTN will allow live donations or only recover a hand or face from someone who is about to die.

Response: VCAs meet the definition of organs based on this rule and are no different from any other organs previously listed under NOTA and the OPTN final rule. Each transplant center has its own selection criteria for accepting potential candidates for VCA transplant and placing them on the waiting list. The OPTN final rule provides specific allocation performance goals (42 CFR 121.8(b)), including: “Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals

⁹ Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. “The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome”, *American Journal of Transplantation*, (2014): 44, <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf>

¹⁰ See 78 FR 40033 available at <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network>.

to, and removing candidates from, organ transplant waiting lists.” The demographic categories mentioned by the commenter are not criteria utilized for placement on the organ wait list.

Live donor organs are addressed by OPTN policies. The most common are kidney and liver. Although a potential living donor may express a desire to donate a VCA, no transplant center currently provides this service. Organs are not procured in the U.S. from any person “who is about to die,” but in fact are obtained either willingly from a living donor or from a person who is already dead (deceased donor) with proper authorization.

Membership

The membership criteria for VCA programs is not specific to deceased or living donation; they apply to both. Therefore, a transplant program could apply to perform living donor VCA transplants.

Allocation of VCAs

The allocation changes in this proposal (elimination of Policy 5.9 (Allocation of Other Organs) and the creation of Policy 12 (Allocation of Vascularized Composite Allografts)) are both specific to deceased donors.

Donor Authorization

Subsequent to Board approval of the interim policies, a question was raised regarding the scope of the changes in Policy 2.12.C regarding the recovery of VCAs for transplant. Committee leadership has clarified that these are meant to be specific to deceased donors and expects the Committee to approve clarifying language in post-public comment. This is consistent with the structure of the current policy, which is a subsection of Policy 2 (Deceased Donor Organ Procurement).

Implementation Exemptions

As mentioned above, some sections of policy were exempted for VCAs due to logistical limitations within the timeframes required to implement this regulatory change. Exemptions in Policies 14.6 and 18.1 impact living donor transplants. These policy requirements will be restored as programming is put into place. Additionally, there will likely be new policies needed regarding living donors and VCAs. Those policy changes will be in future policy proposals.

Expected Impact on Specific Patient Populations:

In February, 2014, all U.S. OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

Expected Impact on OPTN Strategic Plan and Adherence to OPTN Final Rule:

This proposal meets five of the six goals outlined in the OPTN Strategic Plan:

- Goal 1: Increase the number of transplants
- Goal 2: Increase access to transplants
- Goal 3: Improve survival for patients
- Goal 4: Promote transplant patient safety
- Goal 6: Promote the efficient management of the OPTN

Establishing a system for VCA transplantation addresses the key goals outlined above by:

- Providing consistency and structure to VCA policies and programs.
- Improving access to VCA transplantation for patients who might benefit by clarifying VCA donor authorization and related protocols.
- Facilitating the development and exchange of information about candidate appropriateness for transplant, available VCA donors and candidates, and candidate prioritization.
- Helping to maximize the number of VCAs recovered for transplant and promote the best use of donated organs.
- Developing guidance for the evaluation and management of VCA candidates.
- Addressing the changing field of transplantation by responding to a new area of organ allocation policy development.

Plan for Evaluating the Proposal:

The following data will be monitored:

- The number of VCA candidates and transplants by region, by center, and by basic demographics (e.g., VCA organ type, age, gender, ethnicity, ABO blood group, CPRA)
- Reasons for bypass or refusal of VCA organ offers

Additional Data Collection:

Additional data collection is required as a result of this proposal. At this time, donor and potential recipient matching through DonorNet® is not available for VCA organs and will require significant programming changes in the future. In the meantime, an interim solution has been developed. The following worksheets must be submitted by approved VCA transplant programs in order to register VCA candidates on the OPTN waiting list and remove the candidates from the list:

- Contact information for transplant program staff to receive organ offers (**Exhibit A**)
- Candidate registration (**Exhibit B**)
- Candidate removal (**Exhibit C**)

A spreadsheet of VCA candidates is maintained by OPTN and is updated when VCA candidates are added or removed.

Expected Implementation Plan:

The proposed policy and bylaw modifications were effective upon implementation of the modified Final Rule on July 3, 2014. The changes were proposed with a “sunset” date and will expire on September 1, 2015.

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would lift the subset clause on the bylaws and policies already in place – thereby making them permanent bylaws and policies.

Communication and Education Plan:

The VCA Committee advised that a comprehensive educational plan, as well as timely communication and notice to members and the public, will be critical to prevent misconceptions about VCA donor authorization and any application to deceased donor transplantation. A resource document for OPTN members, differentiating VCA donor authorization from authorization for other organs donation, has been developed for usage during the interim policy development period. This resource document was distributed to the OPO community in advance of the July 3, 2014 transition date. Immediate educational and instructional efforts will address the new VCA requirements, with ongoing support and instruction provided to members as the VCA policy framework is developed and refined.

Information about the new requirements also will be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated. In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notices
- System notices
- Member e-newsletter/blog articles
- Public Comment webinars

Compliance Monitoring:

This proposal would make permanent the temporary VCA policy structure which will be used for the 18 month interim policy period. The proposed language will not add new routine monitoring of OPTN members. Any data entered in UNetSM may be subject to OPTN review, and members are required to provide documentation as requested. Additionally, UNOS Membership staff and reviewers from the OPTN/UNOS Membership and Professional Standards (MPSC) Committee will review VCA transplant program application letters to ensure minimum program requirements are met prior to approval.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

OPTN Bylaws Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

The following provisions of Appendix D do not apply to VCA transplant programs:

- D.4: Transplant Program Director
- D.5: Transplant Program Key Personnel
- D.6: Changes in Key Transplant Program Personnel
- D.9: Review of Transplant Program Functional Activity
- D.10 A: Transplant Program Survival Rates
- D.10 B: Patient Notification Requirements for Waiting List Inactivation
- D.10 G: Relocation of Transfer of Designated Transplant Programs.

D.2 Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program ~~for at least one of the organ types involved in multi-visceral transplant.~~ In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

APPENDIX J: ~~RESERVED~~ Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.

J.1 Letter of Notification

If a transplant hospital member commits to performing VCA transplants the hospital must send written notification of this intent to the OPTN Contractor. The notification to the OPTN Contractor

must include a written assurance from the local OPO that it will provide organs for use in vascularized composite allografts.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution
2. A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction
3. A transplant physician or transplant surgeon at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation

Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

The following provisions of Appendix D do not apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status.*

Appendix M: Definitions

D

Designated Transplant Program

An organ-specific program that has been approved by the 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, ~~and~~ intestines, and vascularized composite allografts. 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.

O

Organ

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

V

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

Policy 1.2 Definitions

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

O

Organ

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

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 Vascularized Composite Allografts.*

V

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

W

Waiting list

The computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

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. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.
15. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.12.C Authorization Requirement

Organ recovery teams may only recover organs that they have received authorization to recover. An authorized organ should be recovered if it is transplantable or a 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. This policy does not apply to VCA transplants.

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

5.2 Maximum Mismatched Antigens

A transplant program may also specify the maximum number of mismatched antigens it will accept and any unacceptable antigens for any of its candidates. If a transplant program specifies these mismatched antigens, the OPTN Contractor will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified. This policy does not apply to VCA transplants.

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 recipients in the order that the potential recipients 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 their candidates' data with the OPTN Contractor. The host OPO may run an updated match run and allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to Policy 6: Allocation of Hearts and Heart-Lungs and Policy 10: Allocation of Lungs.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the Organ Export Verification Form to the OPTN Contractor prior to exporting deceased donor organs.

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

5.5.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 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 compatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation).

5.5.B Time Limit for Acceptance

A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.

Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to Policy 2.3: Evaluating and Screening Potential Deceased Donors. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to VCA transplants.

Policy 12: Allocation of Vascularized Composite Allografts

12.1 Waiting Time

Waiting time for VCA candidates begins when the candidate is registered on the waiting list. 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 VCA Allocation

The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:

1. Candidates that are within the OPO's region.
2. Candidates that are beyond the OPO's region.

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

When a VCA is allocated, the host OPO must document 1) how the organ is allocated and the rationale for allocation and 2) any reason for organ offer refusals.

14.6 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the Living Donor Feedback Form. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the Living Donor Feedback Form with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

This policy does not apply to VCA transplants.

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. Table 18-1 shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased Donor Registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either</i> of the following: <ul style="list-style-type: none"> • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the <i>recipient feedback</i> 	For each transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	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	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor organ recovered at the hospital

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	<i>See Policy 18.5.A: Reporting Requirements after Donation</i>	For each living donor organ recovered at the hospital
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24-hours after the transplant	For each recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30-days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	For each recipient, with a reported malignancy, that is followed by the hospital
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30-days after the transplant hospital registers the candidate on the waiting list	For each 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 Contractor. Timely data on recipients is based on recipient 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.

This policy does not apply to VCA transplants.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	<i>Living donor follow-up (LDF)</i>	within the 60-days prior to or after the form due date

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 Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report this information. The OPO or the OPTN Contractor 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 Contractor 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 VCA organ offers; instead, members must document VCA offers according to Policy 12.2: VCA Allocation.