OPTN/UNOS Vascularized Composite Allograft Transplantation Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, Virginia

Sue McDiarmid, MD, Chair
L. Scott Levin, MD, FACS, Vice Chair
Richard Luskin, MPA, Vice Chair

Contents

Action Items **2**
1. Implementation of OPTN's Oversight of Vascularized Composite Allografts 2

Committee Projects **4**
2. OPTN Vascularized Composite Allograft Data Collection 4
3. Elimination of Policy 5.9 – Allocation of Other Organs 5

Other Committee Work **5**
4. Survey of Current Status of Vascularized Composite Allograft Programs 5
5. Procedures for Facilitating Vascularized Composite Allograft Procurement and Distribution 6

Meeting Summaries **6**

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This report reflects the work of the OPTN/UNOS Vascularized Composite Allograft Transplantation Committee November 2013 to May 2014.

Action Items

1. Implementation of OPTN's Oversight of Vascularized Composite Allografts

Public Comment: Fall, 2014 (Estimated)

The Secretary of HHS expanded the definition of human organs by adding VCAs to the covered list of human organs under the OPTN 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 becomes effective July 3, 2014. This proposal represents the first phase in developing bylaw and policy language to guide VCA transplantation. 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.

These recommended policy changes are being proposed for the OPTN Board of Director's consideration during its June 23-24, 2014 meeting with a sunset date in 2015. Formal public comment on the proposed changes will occur in the fall of 2014, with more permanent recommendations considered by the Board during its June 2015 meeting.

Organ Definition
One of the first tasks for the new committee was to update the definition of an organ in the OPTN Bylaws and Policies to include VCAs. The OPTN/UNOS Vascularized Composite Allograft Transplantation Committee (the Committee) discussed this topic during its January 22 teleconference and February 25 in-person meeting. During its February meeting, the Committee unanimously supported (16 support, 0 oppose, 0 abstentions) a motion to submit proposed OPTN Policy language, provided in **Exhibit A**, for the Board of Director's consideration at its June 2014 meeting. The OPTN's definitions will mirror the definitions used in the Final Rule. Due to the final rule modification timeline, these proposed policies have not been distributed for public comment, but will be distributed during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

VCA Membership
The OPTN Bylaws contain numerous membership requirements that must be in place at the transplant hospital before the hospital may be involved with transplantation. In anticipation of the July 3, 2014 implementation of modifications to the OPTN final rule, membership requirements are necessary for programs involved with VCA transplantation. The Committee unanimously supported (14 support, 0 oppose, 0 abstentions) a motion to submit proposed OPTN Bylaws language, provided in **Exhibit A**, for the Board of Director's consideration at

its June 2014 meeting. Due to the final rule modification timeline, these proposed policies have not been distributed for public comment, but will be during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

The Committee has also formed a subcommittee that is working on more in-depth and long term VCA program membership requirements.

VCA Allocation
Upon the July 3, 2014 implementation of modifications to the OPTN final rule, there will be no OPTN policy pertaining to the allocation of VCAs. Much more rigorous discussion is necessary to develop a refined system; in the interim, the Committee recommends a basic allocation framework to guide allocation and deflate potential critiques of allocation by preferential treatment. At its May 9, 2014 meeting, the Committee unanimously supported a motion (14 support, 0 oppose, 0 abstentions) to submit proposed OPTN Policy language, provided in **Exhibit A**, for the Board of Director's consideration at its June 2014 meeting. Due to the final rule modification timeline, these proposed policies have not been distributed for public comment, but will be during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

Vascularized Composite Allograft Donor Authorization
Committee discussion revealed that organ procurement organizations (OPOs) obtain authorization to recover VCAs separately from the authorization to recover other organs for transplant. Although this is a standard practice currently, the Committee believes that a formal policy to codify this practice is necessary to address potential concerns from the public about individuals who have registered to be organ donors but likely did not consider the possibility of donating vascularized composites for transplant. With this, the Committee will offer a resource document to OPOs in tandem to the proposed policy language, provided in **Exhibit A**. The Committee's concerns prompted it to support unanimously (11 support, 0 oppose, 0 abstentions) a motion to send proposed OPTN Policy language regarding VCA donor authorization, provided in **Exhibit A**, for the Board of Director's consideration at its June 2014 meeting. Due to the final rule modification timeline, these proposed policies have not been distributed for public comment, but will be during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

Other Implementation Considerations
In anticipation of the pending Final Rule and OPTN/UNOS Bylaws and Policy changes, UNOS staff reviewed the Policies and Bylaws for any additional requirements that could not be implemented immediately upon the Final Rule amendment. Many of the OPTN/UNOS policies are not organ specific and will apply to VCAs unless the Board specifically exempts them. Several of our computer systems, on the other hand, are organ specific. There are two areas that account for several of these differences:

1) Some of our data collection systems need updates to collect VCA information; and
2) We have a process to facilitate the allocation of VCAs but there won't be a "match run." The use of a "match run" flows through several policies.

Staff are working to update these systems but they're not all going to be implemented by July. Similar to the elimination of the "Allocation of Other Organs" policy, we want to ensure

1) that all of the policies that will apply to VCAs can be implemented and 2) that we don't unnecessarily eliminate any of the existing safeguards that apply to all other organs. At its May 9, 2014 meeting, the Committee unanimously supported a motion to exempt several Policy and Bylaw requirements from VCA transplants. Due to the final rule modification timeline, these proposed policies have not been distributed for public comment, but will be during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

RESOLVED, that additions and modifications to Policies 1.2 (Definitions), 2.2 (OPO Responsibilities), 2.12.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.A (Nondiscrimination in Organ Allocation), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 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, and Bylaws Appendices D (Membership Requirements for Transplant Hospitals and Transplant Programs), D.2 (Designated Transplant Program Requirement), J (Membership Requirements for Vascularized Composite (VCA) Transplant Programs, K (Transplant Program Inactivity, Withdrawal, and Termination), M (Definitions), as set forth below, are hereby approved, effective July 3, 2014.

FURTHER RESOLVED, these additions will expire on September 1, 2015.

Committee Projects

2. <u>OPTN Vascularized Composite Allograft Data Collection</u>

Public Comment: *Spring, 2015 (estimated)*
Board Consideration: *November, 2015 (estimated)*

Data pertaining to VCA transplantation is needed for future development and refinement of VCA allocation policy. The Committee needs to determine which data elements will be necessary to collect for VCA transplants.

During its February 25th meeting, UNOS staff presented the OPTN/UNOS Principles of Data Collection and a general review of all the data currently collected by the OPTN. The Committee was also informed about the public comment process and Office of Management and Budget review that is necessary for the collection of new data. The Chair recommended that the Committee aim for fall public comment to propose VCA data elements to be collected. The Committee will also likely recommend retrospective collection of these data elements for all VCA transplants that occurred prior to the OPTN collecting these data. The Committee believes information about more of these transplants will be helpful, and that this additional data burden will be minimal, because of the small total number of VCA transplants performed thus far. This proposal will also serve to alert programs currently transplanting VCAs what will be collected, and allow them to prepare for the OPTN's impending collection of data pertaining to VCA transplants.

Data collection forms are generated through other processes in UNet℠, e.g., match runs trigger recipient forms. As such, it may be necessary to simultaneously build the data collection system with other UNet℠ functions. Programming of the system will be an

ongoing discussion, and the Committee should proceed to determine what data need to be collected for VCA transplants as the programming plan is developed.

The Committee will begin with reviewing each data element currently collected by the OPTN to determine what should also be collected for VCA transplants. The Committee will then decide what data elements unique to VCA will also need to be collected. A VCA Data Subcommittee was formed and will meet on May 28, 2014. It will review data currently collected by the OPTN and then make recommendations for the full Committee's consideration.

3. Elimination of Policy 5.9 – Allocation of Other Organs

Public Comment: Fall, 2014 (estimated)

The Committee discussed the OPO Committee's project to eliminate Policy 5.9 (Allocation of Other Organs). Policy 5.9 addresses the "allocation of other organs not specifically addressed in other policies." If Policy 5.9 is not edited, implementation of the modified OPTN Final Rule will render VCAs as "organs not specifically addressed in other policies," causing undue complications for OPOs allocating VCAs. The OPO Committee will be proposing at the June 2014 Board of Directors meeting that Policy 5.9 be deleted. After discussing the implications of Policy 5.9, the Committee voted unanimously (14 support, 0 oppose, 0 abstentions) to support the OPO Committee in its recommendation to delete Policy 5.9. Similar to the other policy modifications related to the implementation of VCA oversight, this OPO Committee's proposal will be distributed for public comment in the next public comment cycle.

For more information, see the **OPO Committee's report to the Board.**

Other Committee Work

4. Survey of Current Status of Vascularized Composite Allograft Programs

At its February meeting, the Committee reviewed the results of a survey conducted by the Association of Organ Procurement Organizations (AOPO). The purpose of this survey was to assess the level at which hospitals are currently transplanting VCAs, or planning to in the near future.

AOPO received responses from every OPO. The results of the survey show that there have been 28 VCA transplant recipients transplanted at 11 different transplant centers. Of the 28 transplants performed, 6 were face transplants, 7 were bilateral upper extremities, 14 were unilateral upper extremities, and 1 was a multiple VCA transplant – a face and a unilateral upper extremity.

In addition to transplants already performed, there are currently 9 patients at 6 different transplant centers waiting for a VCA transplant: 4 are awaiting a face transplant, 4 are awaiting a bilateral upper extremity transplant, and one is 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. The Committee recognized this as a good reference for its discussions pertaining to OPTN membership for VCA programs.

5. **Procedures for Facilitating Vascularized Composite Allograft Procurement and Distribution**

   The Committee also needs to develop policies to guide OPO and transplant center interactions throughout all the processes of a VCA transplant, e.g. donor exclusion criteria, packaging requirements for shipping recovered organs, etc. Similar to determining what data elements need to be collected, the Committee will first review current OPTN policies for other organs.

   OPO representatives on the Committee volunteered to initiate this effort by drafting a guidance document to inform developing VCA programs of all the necessary considerations for facilitating a VCA transplant. This draft will then be discussed further by the Committee.

Meeting Summaries

The committee held meetings on the following dates:

- January 22, 2014
- February 25, 2014
- March 25, 2014
- April 29, 2014
- May 9, 2014

Meeting summaries are available on the OPTN website at:
http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=140.

BRIEFING PAPER **OPTN/UNOS**

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

Table of Contents

Proposal to Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs) 2
Sponsoring Committee: Vascularized Composite Allograft (VCA) Transplantation Committee .. 2
Summary and Goals of the Proposal: 2
Background and Significance of the Proposal: 2
Supporting Evidence and/or Modeling: 4
Expected Impact on Living Donors or Living Donation: 5
Expected Impact on Specific Patient Populations: 5
Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule: 5
Additional Data Collection: 13
Expected Implementation Plan: 14
Communication and Education Plan: 14
Compliance Monitoring: 14
Policy Proposal 15

BRIEFING PAPER **OPTN/UNOS**

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

Sponsoring Committee: Vascularized Composite Allograft (VCA) Transplantation Committee

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). The proposed policies outline the following:

- Definition of covered body parts in any policies specific to VCA transplantation,
- VCA transplant program membership criteria,
- Allocation of VCA organs,
- Authorization for VCA organs distinct from other whole organ transplants, and
- Other policy and bylaw modifications that would specifically exempt applicability to VCA transplantation

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 becomes effective July 3, 2014. This proposal represents the first phase in developing bylaw and policy language to guide VCA transplantation. 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 changes are being proposed with a sunset date and will expire on September 1, 2015, with formal public comment following in fall of 2014. Formal public comment on the proposed changes will occur in the fall of 2014, with more permanent recommendations considered by the Board during its June 2015 meeting.

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

[1] Vascularized composite allotransplantation: An update on medical and surgical progress and remaining challenges ☆ Blake D. Murphy[a], Ronald M. Zuker[a, b], Gregory H. Borschel[a,] J Plast Reconstr Aesthet Surg. 2013 Nov;66(11):1449-55. doi: 10.1016/j.bjps.2013.06.037.

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 type 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. This effort needs to be addressed *prior* to the June 2014 OPTN/UNOS Board of Directors (BOD) meeting so that the recommendations can be considered before implementation of the modified OPTN Final Rule.

Under the Final Rule, the OPTN is required to submit proposed policies for review and approval by the Secretary of HHS, who may then determine which of the proposed policies should be made enforceable. Any OPO or transplant hospital found to be in noncompliance with any policy approved as enforceable by the Secretary is subject to potential sanctions. Including VCAs as covered organs under the OPTN modified Final Rule will allow the Secretary to take appropriate enforcement actions against an OPO or transplant hospital for failing to comply with any OPTN VCA policy, and subject the member to the same consequences as noncompliance with OPTN deceased donor transplantation policies. Therefore, it is necessary for VCAs to be clearly distinguished as organs, with covered program components defined within the OPTN policy framework, to ensure that VCA policies are consistent with the Final Rule.

The OPTN Vascularized Composite Allograft Transplantation Committee (VCA Committee), comprising representation from US transplant programs currently performing clinical VCA transplantation and the major transplant and procurement societies, discussed and proposed policy and bylaw recommendations for the major areas identified for initial VCA program oversight. Over several conference calls held during the period 1/22/2014-5/9/2014, the VCA Committee and subcommittees reviewed and discussed internal processes of transplant programs involved in VCAs. 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. The VCA Committee worked closely with OPTN staff to develop the necessary components with applicable policy language.

The proposal developed by the VCA Committee establishes minimum requirements for OPTN transplant programs that perform VCA transplantation. The proposal outlines a basic policy and bylaw framework and broad allocation principles for prioritizing candidates and achieving consistency in requirements for the growing number of programs performing VCA transplants. The proposed policy language covers:

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[2] Composite tissue transplantation. Gerald Brandacher, Methods Mol Biol. 2013; 1034: 103–115. doi: 10.1007/978-1-62703-493-7_5.

- Body parts addressed by any OPTN policies specific to vascularized composite allografts
- Minimum essential elements that must be in place at the transplant hospital and approved by the MPSC before the hospital may become involved with VCA transplantation
- Basic VCA allocation sequence
- OPO authorization to recover VCAs separately from the authorization to recover other organs for transplant; and
- Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

The recommended policy modifications are being proposed for OPTN Board of Directors consideration during the June 23-24, 2014 meeting with a sunset in 2015. Formal public comment on the proposed policy will follow in the fall of 2014. The revised VCA policy, incorporating any relevant public comment feedback, will be resubmitted for Board consideration during its June 2015 meeting.

Supporting Evidence and/or Modeling:

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 cosmetic 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, 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) membership 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 the February 2014 meeting, the results of the survey showed:

- 28 VCA transplant recipients were transplanted at 11 different transplant centers. Of the 28 transplants performed, 6 were face transplants, 7 were bilateral upper extremities, 14 were unilateral upper extremities, and 1 was a multiple VCA transplant – a face and a unilateral upper extremity.

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[3] Vascularized composite tissue allotransplantation--state of the art, Diaz-Siso JR, Bueno EM, Sisk GC, Marty FM, Pomahac B, Tullius SG. Clin Transplant. 2013 May-Jun; 27(3):330-7. Epub 2013 Apr 14.

[4] Monitoring and long-term outcomes in vascularized composite allotransplantation. Kaufman CL, Ouseph R, Marvin MR, Manon-Matos Y, Blair B, Kutz JE. Curr Opin Organ Transplant. 2013 Dec; 18(6):652-8.

[5] Allocation of vascularized composite allografts: what is it? Transplantation. 2012 Jun 15;93(11):1086-7. doi: 10.1097/TP.0b013e31824b073f.

- 9 patients at 6 different transplant centers are waiting for a VCA transplant: 4 are awaiting a face transplant, 4 are awaiting a bilateral upper extremity transplant, and one is 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 follow-up 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.

Expected Impact on Living Donors or Living Donation:

None. To date, there have not been any VCA transplants from living donors and none are known to be expected.

Expected Impact on Specific Patient Populations:

Expected impact on specific patient populations is unknown at this time.

Expected Impact on OPTN Key Goals 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
    1) Improving access to VCA transplantation for patients who might benefit by clarifying VCA donor authorization and related protocols
    2) Facilitating the development and exchange of information about candidate appropriateness for transplant, available VCA donors and candidates, and candidate prioritization,
    3) Helping to maximize the number VCAs recovered for transplant and promote best use of donated organs.
    4) Developing guidance for the evaluation and management of VCA candidates.
    5) Addressing the changing field of transplantation by responding to a new area of organ allocation policy development.

VCA Policy Development

Definition of Covered Body Parts Specific to VCA Transplantation

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.

A VCA organ is a body part that is:

1) 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 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 organ 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

[6] OPTN Final Rule 42 CFR 121.2 - Definitions

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.

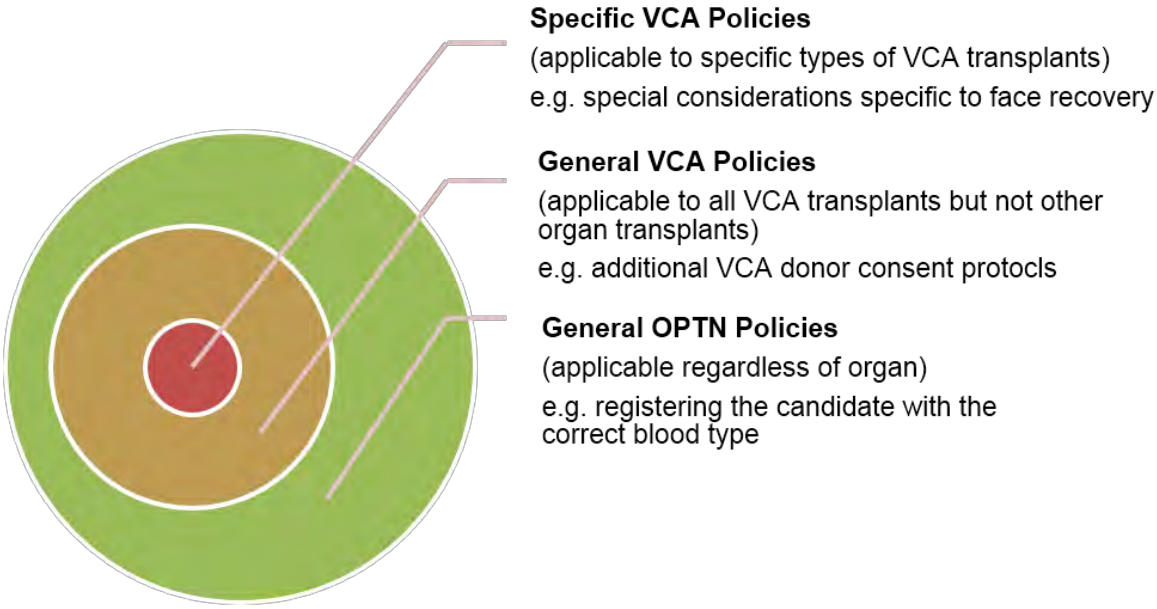

Figure 1: Tiers of OPTN Policy as applicable to VCA transplants.

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 (Approve – 16, Oppose – 0, Abstain – 0) 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 discussions.

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

VCA Transplant Program 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[7], to establish the basic membership requirements for VCA programs that will be sent for the Board's consideration in June. 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 UNet℠ 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. involved in establishing a program. Requiring this exchange with the local OPO would demonstrate that a program has begun the necessary planning to perform VCA transplants.

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

[7]Implementation of Vascularized Composite Allografts in the United States: Recommendations From the ASTS VCA *Ad Hoc* Committee and the Executive Committee, 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. (2011),. American Journal of Transplantation, 11: 13–17. doi: 10.1111.

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 added 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 (Approve – 11, Oppose – 0, Abstain – 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.

No further changes were made to the approved bylaws language during subsequent committee discussions.

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

VCA Allocation Sequence

OPTN Policy 5.9 (Allocation of Other Organs) addresses the "allocation of other organs not specifically addressed in other policies." In a separate proposal, the OPO Committee will recommend that the Board of Directors delete this policy at its June 23-24, 2014 meeting, to avoid application of the language to VCAs following implementation of the modified OPTN Final Rule.

The OPTN 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 should 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. Because it will not be possible to register candidates according to the standard definition of registration in OPTN policy during the interim policy period, it was suggested that the use of "registration" in the second sentence be avoided. 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 option 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 UNet^{SM} during the interim policy period, the manual VCA matching process was loosely outlined for the committee:

1) Transplant programs will register their VCA candidates in a document that they will securely transmit to UNOS.
2) UNOS will compile all of the candidate registrations into a master list which would be distributed to OPOs.
3) OPOs will match VCA donors to candidates using the master list.

4) In the event an OPO identifies a VCA donor that is suitable for more than one candidate from the mast list, allocation will first be offered to regional candidates.
5) If the organ is not accepted regionally, allocation will be offered to national candidates.
6) 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 (Approve – 14, Oppose – 0, Abstain – 0):

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

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, every program that is currently conducting 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.

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 and the committee determines that separate authorization is no longer necessary, the committee may consider eliminating the policy language. 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.

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 (Approve – 11, Oppose – 0, Abstain – 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 UNet℠ 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, not all of these changes will be in place by July 2014. Therefore, policy language has been proposed for specific sections of OPTN policy and the bylaws to ensure that all of the policies applicable to VCAs can be implemented and that existing safeguards for solid organs can be preserved. The proposed changes will be considered by the Board in June 23-24, and will expire as solutions can be implemented.

During its May 9th conference call, the VCA Committee reviewed the applicable sections of policy and the bylaws containing the exemption language proposed by UNOS staff and approved all proposed additions.

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. (Approve – 14, Oppose – 0, Abstain – 0)

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

Additional Data Collection:

Data pertaining to VCA transplantation will be needed for future development and refinement of OPTN VCA allocation policy. While the programming plan is being developed, the VCA Committee will review each data element currently collected by the OPTN to determine which should be collected for VCA transplants. As data collection forms are generated through other processes in UNet℠ (e.g., match runs trigger recipient forms, etc.), VCA data collection may be simultaneously built with other UNet℠ functions. The committee also recommended collection

of retrospective data due to the limited number of procedures performed to date. The Committee plans to work on developing VCA data collection forms and the recommended data elements for collection will be distributed for a future public comment cycle.

Expected Implementation Plan:

The proposed policy and bylaw modifications will take effect upon implementation of the modified Final Rule on July 3, 2014. The changes are being proposed with a sunset date and will expire on September 1, 2015, with formal public comment following in fall of 2014. More permanent recommendations will be considered by the Board during its June 2015 meeting.

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, would be critical to prevent misconceptions about VCA donor authorization and any application to deceased donor transplantation. A resource document differentiating VCA donor authorization from authorization for solid organ transplantation, has been developed for usage during the interim policy development period. (See **Appendix A**.) 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:

1. Policy notice
2. System notice
3. Member e-newsletter/blog articles
4. Notification to a list serve group for transplant administrators

Compliance Monitoring:

This proposal presents a temporary VCA policy structure which will be used while a more complex structure is developed. No active compliance monitoring will occur under the temporary structure. In the interim, the UNOS Department of Evaluation and Quality (DEQ) staff will investigate any reported violations of VCA policy, until more permanent VCA recommendations and accompanying compliance monitoring plan are developed.

Policy Proposal

Presented below are the approved modifications to OPTN policy and bylaw language for the Board of Director's consideration at its June 23-24, 2014 meeting.

Due to the Final Rule modification timeline, these proposed changes to policy and the bylaws have not been distributed for public comment prior to Board consideration, but will be distributed during the next public comment cycle occurring in the Fall of 2014. For this reason, it is recommended that the changes be adopted with an expiration date.

Policy or Bylaw Proposal:

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

RESOLVED, that additions and modifications to Policies 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), 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, and Bylaws Appendices D (Membership Requirements for Transplant Hospitals and Transplant Programs), D.2 (Designated Transplant Program Requirement), J (Membership Requirements for Vascularized Composite (VCA) Transplant Programs, K (Transplant Program Inactivity, Withdrawal, and Termination), M (Definitions), as set forth below, are hereby approved, effective July 3, 2014.

FURTHER RESOLVED, these additions will expire on September 1, 2015.

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:

- That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
- Containing multiple tissue types;
- Recovered from a human donor as an anatomical/structural unit;
- Transplanted into a human recipient as an anatomical/structural unit;
- 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);
- 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);
- Not combined with another article such as a device;
- Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
- Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

W

Waiting list

A~~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:

- Identifying potential deceased donors.
- Providing evidence of authorization for donation.
- Evaluating deceased donors.
- Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
- Verifying that death is pronounced according to applicable laws.
- Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
- Clinical management of the deceased donor.
- Assuring that the necessary tissue-typing material is procured, divided, and packaged.
- Assessing deceased donor organ quality.
- Preserving, packaging, and transporting the organs.
- Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
- 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.
- Documenting and maintaining complete deceased donor information for seven years for all organs procured.
- 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.
- 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:

- The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
- The match system ranks candidates according to the allocation sequences in the organ allocation policies.
- OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
- 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.
- 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.
- 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	*Donor histocompatibility* (DHS)	30-days after the OPO submits the deceased donor registration	For each 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*	For each 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	For 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	For all deaths reported by a hospital to the OPO

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Allocating OPO	*Potential transplant recipient* (PTR)	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	*Deceased donor feedback*	5 business days after the procurement date	
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	*See Policy 18.5.A: Reporting Requirements after Donation*	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	• 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	For each recipient followed by the hospital

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-hours after the transplant	For each 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	For each 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	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.

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.

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:

5. *D.4: Transplant Program Director*
6. *D.5: Transplant Program Key Personnel*
7. *D.6: Changes in Key Transplant Program Personnel*
8. *D.9: Review of Transplant Program Functional Activity*
9. *D.10 A: Transplant Program Survival Rates*
10. *D.10 B: Patient Notification Requirements for Waiting List Inactivation*
11. *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:

- The chief administrative officer for the institution
- A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensiveexperience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction
- A transplant specialist who has current qualification as a transplant physician or transplant surgeon and has completed an approved transplant fellowship 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:

12. *K.1: Transplant Program Inactivity*
13. *K.2: Short-term Inactive Transplant Program Status*
14. *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.

Resource Document for Vascularized Composite Allograft (VCA) Donor Authorization

Preserving the public trust in the process of organ donation is of the highest priority. The recent designation of VCA as an "organ" requires careful consideration of how this public trust can best be maintained while facilitating appropriate authorization for VCA donation. It is critical to recognize that the public is unlikely to be aware that VCAs are now regarded as an organ that may be donated for transplantation when authorizing organ donation through a donor, or when a family is approached in the absence of prior donor authorization. Concerns regarding the sensitivity of the approach to donation requests for VCA were explicitly addressed by the Secretary of Health and Human Services in the Federal Register (Volume 78 Number 128, July 3, 2013) Action: Final Rule

"…questions of public trust may arise if transparency is not kept at the forefront at every phase of the donation process. For this reason the Secretary encourages explicit consent for VCA from prospective donors (or next of kin) and as such consent be as clear and meaningful as possible…"

The OPTN/UNOS VCA Committee has provided specific language reflective of this concern. In discussing the appropriate policy language the committee the Committee recognized that authorization to recover donated organs is governed by state laws under the Uniform Anatomical Gift Act and as such the OPTN/UNOS policy should not conflict with existing and well-established state law. This includes the principle that prior authorization for organ donation is legally binding.

Accordingly, the VCA Committee policy language intentionally seeks to ensure transparency in the donation request by requiring that donor authorization for VCA, whether given by the donor prior to death, or by family as surrogate decision makers, must be explicit and specific for VCA donation. Authorization for VCA donation should not be assumed under the general term 'organ' donation.

Taking into consideration these principles, the Committee's proposed policy language is as follows:

Policy 2.12C VCA Authorization Requirement

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

The committee acknowledged that a thoughtful education effort is necessary to address the concerns and perceptions that are the underlying rationale for a specific VCA donor authorization policy. This educational effort should be directed at OPOs and other designated requestors, as well as staff at local donor hospitals and administrators, as well as the public. To

aid in this educational effort and to provide best practices for OPO, the Committee has developed this resource document.

Guiding Principles and Best Practices

1) If prior donor authorization is in place either through a recognized donor registry (DMV or otherwise) or other signed document recognized under applicable UAGA state law, the OPO staff will determine if the authorization explicitly states the desire to donate a VCA. Currently, very few donor registries provide an opportunity to specifically authorize VCA, although this may change in the future. Donor authorization through the Department of Motor Vehicles donor registries currently does not include an opportunity to specifically authorize VCA donation. If authorization for donation is being requested from a surrogate decision maker, the donation request and authorization needs to explicitly and specifically identify VCA donation as compared to traditional solid organs or tissues.

2) In discussing general concepts of organ donation with a potential donor family when no prior authorization for donation exists, it is recommended, that in general, authorization to recover VCAs should be addressed separately and sequentially to avoid the possibility that all authorization for recovery of traditional lifesaving whole organs is denied because the donor family is unaware of, or uncomfortable with the idea of visible body parts being used for VCA donation. This recommendation is supported by the current practice of OPOs with experience requesting VCA authorization to first obtain authorization for traditional whole organ donation followed by a separation discussion and specific request for VCA donation.

   In all cases of VCA donation, the donor family should be educated about VCA donation and transplantation. The following key elements should be addressed:

   - Clearly define and explain what is a vascularized composite allografts, the benefit to the recipient and an explanation of exactly what may be recovered.

   - Be sure the next of kin understand that the donor will look very different after recovery depending on the VCA procured and that the VCA surgical recovery team will perform re-construction in accordance with the family's wishes in the preparation for the donor's burial. This may include a face mask molded from the donor's own features, or a prosthetic hand or upper extremity.

   - Clear communication that the donor's identity will be protected to the extent possible but factors such as identifying skin markings, i.e. "birthmarks" and fingerprints for upper extremity procurements, may limit the ability to keep all donor information confidential. Further, the recipient's identity will likely be known to the donor family if the recipient decides to be public about the VCA transplantation. This may unintentionally compromise the anonymity of the donor.

- Clear communication to the family that prior general authorization by the potential donor to recover "organs" does not include authorization to recover a VCA unless explicitly stated.

3) OPOs should develop a donor authorization form that specifically identifies the option of VCA donation. Strong consideration should be given to a separate VCA donor authorization form that also includes educational aspects of VCA and specifically acknowledges and documents that the family understands the relevant anatomical details of the VCA, the alteration in the physical appearance of the donor, and the possibility that donor anonymity may not be protected despite best intentions of the OPO.

Appended to this resource document are examples of donor authorization form already developed by OPOs that document the separate donor authorization for VCAs that maybe useful 'templates' for other OPOs to consider or modify.

New England Organ Bank
60 First Avenue, Waltham, MA 02451
Phone 800-446-6362 / FAX 617-244-8755

Authorization for Vascularized Composite Allograft Donation

I/We _____ as _____ of
(Name of next of kin) (Relationship)

_____ hereby authorize and direct that upon death a gift of the following vascularized composite allograft (s) be made to the NEW ENGLAND ORGAN BANK (NEOB), a non-profit organization, for use in transplantation:

Facial and Forearm grafts	Yes □	No □	N/A □				
Right Hand and Arm graft	Yes □	No □	N/A □	Left Hand and Arm graft	Yes □	No □	N/A □
Right Foot and Leg graft	Yes □	No □	N/A □	Left Foot and Leg graft	Yes □	No □	N/A □

- The facial graft may include skin/mucosa, underlying muscles and nerves, blood vessels and fat tissue of the nose, lips and surrounding cheek. The facial graft may be small or may be a significant portion of the donor's facial tissue depending on the need of the individual recipient.
- The forearm graft which will be recovered only with a facial graft will include skin, the radial artery and vein and some fat tissue located under the skin. This graft will be recovered from the palm side of the forearm just above the crease of the wrist. This will be used as a biopsy site to test for rejection of the facial graft.
- The hand and arm graft(s) may include skin, underlying muscles and nerves, blood vessels and bone. Additionally blood vessels of the leg(s) may be recovered if additional length of vascular grafting material is deemed necessary.
- The foot and leg graft(s) may include skin, underlying muscles and nerves, blood vessels and bone.
- The hand and arm graft(s) may be as short as from the wrist to the fingertips or as long as from shoulder to the fingertips. The foot and leg graft(s) may be as short as from the ankle to the tips of the toes or as long as from the hip to the tips of the toes. The size and length of the graft will be dependent on the need of the individual recipient as determined by the transplanting surgeon.

- I/We agree that tissue recovered (including skin, blood and lymph nodes) that are not used for transplantation may be stored for future research use related to transplantation.

  □ yes □ no

- I/We are not aware of any objection to this gift of a vascularized composite allograft by the patient or any person of a higher or equal legal status authorized to make a donation decision under applicable law.
- I/We understand that this donation of the vascularized composite allograft will significantly alter the appearance of the donor. In the case of a facial graft, a skin-colored silicone mask designed to match the donor's skin tone will be used to cover the areas where the facial graft was removed from the donor's face. In the case of hand, arm. foot and/or leg graft(s), a skin-colored prosthetic designed to match the donor's skin tone will be utilized.
- I/We understand that vascularized composite allograft in New England may receive media attention which will not be in NEOB's control.
- I/We understand that the recipient's identity may be disclosed to the media including images and pictures of the recipient before and after the transplant. Such media coverage could include print, audio, visual and electronic. NEOB has no control over and is not responsible for media coverage related to the recipient.
- I/We understand that NEOB cannot guarantee that the identity of the donor will remain confidential. It is possible that over time the donor's identity will be discovered and disclosed to third parties including the media despite NEOB's efforts to keep this information confidential.

Authorization for Vascularized Composite Allograft Donation

Name of donor: _____

Signed this _____ day of _____, 20_____

Time: _____

_____
Name/Relationship (print)

_____
Signature

_____
Address/Telephone

WITNESS TO AUTHORIZATION

_____
Name

_____
Signature

_____
Address/Telephone

Person requesting authorization: (print) _____ (signature) _____
(New England Organ Bank Staff)

Telephone Authorization for Vascularized Composite Allograft Donation
(This discussion must be recorded)

I have spoken with the following person, who authorized the donation of the vascularized composite allograft(s) listed above for the purpose(s) noted above.

Name_____ Relationship to donor_____

Address_____

Telephone number called (_____)_____

Name of requestor (print)_____ Date/Time_____
New England Organ Bank Staff

Signature _____

Name of Witness to Authorization (print)_____Date/Time_____

Signature_____ Recorded on extension: _____