At-a-Glance

- **Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation**

- **Affected/Proposed Policy:**
  - Policy 2.0 — Minimum Procurement Standards for an organ Procurement Organization
  - Policy 3.3 — Acceptance Criteria
  - Policy 3.5 — Allocation of Deceased Kidneys
  - Policy 5.0 — Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials
  - Policy 6.0 — Transplantation of Non-Resident Aliens
  - Policy 7.0 — Data Submission Requirements
  - Policy 9.0 – Release of Information to the Public
  - Attachment III to Appendix B of the OPTN Bylaws — Model Elements for Controlled Donation after Cardiac Death Protocols

- **Organ Procurement Organization (OPO) Committee**

  Currently, UNOS policy uses the term "consent" to describe the act of making an anatomical gift. However, the public associates "consent" with the medico-legal concept of "informed consent" through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

  In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from "consent" to "authorization." This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

- **Affected Groups**

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

- **Number of Potential Candidates Affected**
  Although there is no affect on potential candidates regarding their ability to receive a transplant, all individuals that are part of the donation and transplantation community are affected by this change.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This change is in keeping with the HHS Program Goal of "Operational Effectiveness." The Committee believes that this change is a system improvement in that it aligns policy with practice that supports critical network functions.

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Summary and Goals of the Proposal:

Currently, UNOS policy uses the term "consent" to describe the act of making an anatomical gift. However, the public associates "consent" with the medico-legal concept of "informed consent" through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from "consent" to "authorization." This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

Background and Significance of the Proposal:

During the past several years, the OPO community became aware that the term "consent" for organ/tissue/eye donation is widely perceived by the general public, and by hospital and other healthcare workers, to have the same meaning as "informed consent." The medical concept of informed consent however does not apply to the way anatomical gifts are made. The confusion arises, however, because organ/tissue donation always takes place in a healthcare setting when the donor has been or is undergoing medical or surgical treatment and the donor's family is dealing with an unexpected and often traumatic death.

Statutes, regulations and courts define the medical concept of "Informed consent" to mean that a physician must disclose and discuss the following with a patient:

- Patient's diagnosis, if known
- Nature and purpose of a proposed treatment or procedure
- Risks and benefits of a proposed treatment or procedure

- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance)
- Risks and benefits of the alternative treatment or procedure
- Risks and benefits of not receiving or undergoing a treatment or procedure

In turn, patients should be able to ask questions to gain a better understanding of the treatment or procedure, so they can make an informed decision about whether or not to proceed with a particular course of medical intervention. In some instances, for example, surgery or other invasive procedures, the law provides that these disclosures be made in writing and must be acknowledged by the patient or the patient's representative.

This communications process, or some variation, is not only a legal duty; it also is an ethical obligation prescribed by the Code of Medical Ethics of the American Medical Association ("Code of Ethics")[1]. The Code of Ethics states that the informed consent of a patient or other recipient of services is based on the principles of autonomy and privacy and has become the requirement at the center of morally valid decision making in health care and research. The following seven criteria define informed consent:

1. Competence to understand and to decide,
2. Voluntary decision making,
3. Disclosure of material information,
4. Recommendation of a plan,
5. Comprehension of terms (3) and (4),
6. Decision in favor of a plan, and
7. Authorization of the plan.

A person gives informed consent only if all of these criteria are met. If all of the criteria are met except that the person rejects the plan, that person makes an informed refusal.

By contrast, when an individual decides to become an organ, eye, and tissue donor, the setting is entirely non-medical. The individual who applies for a driver's license is requested by a web page, or by Department of Motor Vehicles (DMV) staff or by a letter from the DMV to designate him or herself as a donor. Still others find their way to a donor registry or include their wishes in an advance directive, will, or some other signed document. They are not being asked to commit themselves to a course of conduct that may have significant consequences for their survival or quality of life, and the decision, more likely than not, is made without interacting with a donation professional. OPOs have a responsibility to educate the public about organ, eye, and tissue donation. In places and situations where a person may decide to be a donor, OPOs should make sure information is available about the purposes for which the donation may be used. The OPO conveys this information to the prospective donor in various ways: website content, DMV staff and DMV brochures, donor registries, as well as ensuring additional, more detailed information is available. It is not respectful of the donor's decision or helpful to the donation process to view these types of decisions through the prism of medical "informed consent."

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[1] *"Code of Medical Ethics" (American Medical Association, http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.page, June, 2009) April 2011*

If individuals have not made the donation decision themselves, the process of requesting the anatomical gift takes place at a more intensely personal level and in a medical setting – in a hospital at the time of the individual's sudden or unexpected death. OPOs are legally required to advise the persons who have the legal right to make the gift, that is, the person's agent or next-of- kin, of their option to donate or to decline to donate. In giving this advice, OPOs are required to "encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families" and regulations specify what information the OPO is required to convey.[2] The donation decision does not involve a course of conduct that may have significant consequences for the donor's survival or quality of life. Family members, however, are asked to make that decision when they have recently been engaged in a struggle for the donor's life in which the medical concept of "informed consent" is applicable to every decision.

Again, it is not helpful to the family or to the donation process to have the concept of medical informed consent applied to the donation decision. The term "consent" does not accurately reflect the permission granted for donation that occurs in the donation process.

The OPO community requests that the OPTN adopt conforming changes to bring the terminology in all affected UNOS policies and publications into line with actual usage in the donation and transplantation community of practice.

Collaboration:

The OPO Committee and the leadership of the Association of Organ Procurement Organizations (AOPO) have recognized the need for this change in terminology during the last several years and support this change.

Alternatives considered:

As this proposed change is a terminology change designed to update policy and bring it in line with accepted practice, the Committee agreed that this change was an important and necessary step. If the term remains in policy, it will be not be consistent with current practice.

Strengths and weaknesses:

Strength: this proposal brings policy in line with current accepted practice. The term authorization has become the standard for describing the process of authorization for donation.

Weakness: OPOs and possibly transplant centers may wish to modify any policy/protocols dealing with organ donation that use the term "consent" and change it to "authorization." It takes time for OPOs and transplant centers to modify their policies and they may wish to allocate resources to this task.

No additional data collection is required.

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[2] *Code of Federal Regulations (annual edition). Title 42: Public Health, Subjgrp: Organ Procurement Organization Process Performance Measures 42 CFR §486.342 – Condition: Requesting consent. (http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec486-342.pdf. October 1) April, 2011.*

Description of intended and unintended consequences:

The intended consequence is that OPTN policy and bylaws will be consistent with the current terminology used in practice. OPOs and transplant centers may wish to update their own policies and procedures to align with current nomenclature and OPTN policy and bylaws terminology. If so, resources will need to be allocated to the process.

Supporting Evidence and/or Modeling:

It is the expertise and experience of the Committee and the AOPO leadership that supports this proposed policy/bylaws change.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

There is no known impact to donors or candidates.

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

This change is in keeping with the HHS Program Goal of "Operational Effectiveness." The Committee believes that this change is a system improvement in that it aligns policy with practice that supports critical network functions.

Plan for Evaluating the Proposal:

This proposed change is strictly a nomenclature change to align policy language with that used in the community. Members will not be required to change their policies, so no evaluation is needed.

Additional Data Collection:

No Additional Data Collection is required.

Expected Implementation Plan:

OPOs and transplant centers will need to review their current policies and procedures as they may wish to align them with OPTN policy. OPOs and transplant centers will have to follow their respective procedures if they choose to make these changes.

This proposal will require programming in UNet^{SM}.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Standard Policy Notice	OPOs and Transplant Centers	e-newsletter with a link to the policy notice on the member archive.	30 days after the board meeting where the policy proposal was approved.

Monitoring and Evaluation:

No additional monitoring is required

Policy or Bylaw Proposal:

2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

In order to maximize the gift of donation and optimize recipient outcomes and safety, the Organ Procurement Organization (OPO) must comply with the following policies for minimum procurement standards.

2.1 HOST OPO. The OPO responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining ~~consent~~ authorization for the removal of organs, complying with OPTN policy throughout the donation process, and organ allocation.

Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNet^{SM} and that the approved OPTN automated organ allocation computer algorithm is executed for each donor organ.

The Host OPO shall make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor.

The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged.

The Host OPO is responsible for written documentation of donor evaluation, donor maintenance, ~~consent~~ authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 – 2.3 [No Change]**.**

2.4 OBTAINING ~~CONSENT~~AUTHORIZATION. The Host OPO must provide evidence of ~~consent~~ authorization for donation according to applicable legal authority.

2.5 – 2.9 [No Change]**.**

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3.3 ACCEPTANCE CRITERIA

3.3.1– 3.3.5 [No Change].

3.3.6 Center Acceptance of Organ Offers. If an organ is offered and accepted without conditions, the Host OPO and intended recipient's transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

3.3.6.1 Exception for DCD Donor who Converts to Brain Death After an Organ Offer has been Made. When a DCD donor converts to brain death, the match system must be re-executed and organs must be allocated according to policies 3.5 - 3.11. Policy 3.6.5.1 does not apply when a DCD donor converts to brain death. Additionally, OPOs are encouraged to initiate allocation of organs that may have been ruled out due to the donor's DCD status (i.e. heart, lungs, pancreas).

3.3.6.1.1 The Host OPO may choose not to re-allocate organs from a DCD donor who converts to brain death in the following circumstances: 1) lack of donor family approval and ~~consent~~authorization; 2) donor instability; or 3) other extraordinary circumstances. The Host OPO must document the reason for not re-allocating organs when a DCD donor converts to brain death and make this documentation available upon request.

3.5 ALLOCATION OF DECEASED KIDNEYS

3.5.1 – 3.5.3.2 [No Change].

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1] if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1], if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a

candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written ~~consent~~ authorizatrion for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before ~~consent~~ authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until ~~consent~~ authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is ~~consented~~ authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.3 – 3.5.4 5 [No Change].

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.3.4 Organ Offer Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor[1], six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a

payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written ~~consent~~ authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before ~~consent~~ authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until ~~consent~~ authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is ~~consented~~ authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.6 – 3.5.17 5 [No Change].

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

5.1 – 5.4 [No Change].

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

5.5.1 Documentation accompanying the organ

- Complete donor documentation must be sent in the container with each transported organ. This documentation must include:
  - ABO typing source documentation;
  - Infectious disease testing results;
  - Medical/Behavioral History form;
  - Donor Evaluation;
  - Complete record of the donor;
  - ~~Consent~~Authorization form; and
  - Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
  - a location specifically designed for documentation, or
  - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.5.2 Documentation accompanying the vessel

If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the vessels.

5.6 - 5.9 - [No Change].

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 Vessel recovery and transplant

- The ~~consent~~ authorization forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant programs. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.

5.10.2 – 5.11.3 [No Change].

6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS

6.1 - 6.3 [No Change].

6.4 EXPORTATION AND IMPORTATION OF ORGANS-DEVELOPMENTAL STATUS. International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development.

6.4.1 Exportation. Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

6.4.2 Developmental Protocols in International Organ Exchange. After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign

agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the ~~informed consent~~ authorization of the donor or his or her legal representative. Proposed protocols must also include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors.

6.4.3 Ad Hoc Organ Exchange. Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional exchanges must be made as part of an international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.

Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the ~~informed consent~~ authorization of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.

6.4 – 6.5 [No Change].

7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNet^{SM}, beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all ~~consented~~ authorized donors, ~~consent~~ authorized but not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased

Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory. Recipient transplant centers are responsible for submission of Recipient Feedback information, Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, transplanted or followed at the center.

7.1 – 7.9 [No Change].

9.0 RELEASE OF INFORMATION TO THE PUBLIC.

9.1 – 9.6.5 [No Change].

9.6.6 Updated OPO-specific donor procurement volumes, (using data validated by the member through UNet℠, including organ-specific ~~consent~~authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, (using data validated by the member through UNet℠, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.

9.6.7 – 9.12 [No Change].

ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS

Model Elements for Controlled DCD Recovery Protocols

A. **Suitable Candidate Selection [No Change].**

B. ~~Consent~~ Authorization/Approval

1. The legal next of kin may elect to ~~consent to~~ authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without ~~consent~~ authorization.

2. Clearance from medical examiner/coroner must be obtained when applicable.

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3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.

4. For purposes of these model elements, "legal next of kin" shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

C. Withdrawal of Life Sustaining Measures/ Patient Management

1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the

respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.

2. No member of the transplant team shall be present for the withdrawal of life-sustaining measures.

3. No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.

4. There must be a determination of the location and process for withdrawal of life sustaining measures (e.g. ETT removal, termination of blood pressure support medications) as a component of the patient management.

5. If applicable, placement of femoral cannulas and administration of pharmacologic agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed in the ~~consent~~ authorization process.

D. **Pronouncement of Death [No Change].**

E. Organ Recovery [No Change].

F. Financial Considerations [No Change].