At-a-Glance

- **Proposal to Update and Clarify Language in the DCD Model Elements**

- **Affected Bylaw:** Attachment III to Appendix B of the OPTN Bylaws

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

  The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements do not change any current level of oversight by the donor hospital to ensure that appropriate practices are following for a patient's end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. As such, the name Model Elements has been changed to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

  1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
  2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

  Additionally, other policies that have the terms "Donation after Cardiac Death" will be modified for consistency. These proposed changes will help provide a common understanding of DCD protocols for the transplant community and the public.

  Note: *This proposal was distributed for public comment during the March 11, 2011 to June 10, 2011 period. Prior to the Nov. 14-15, 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments. The Executive Committee directed the OPO Committee to review the comments outlined in the letters, revise the proposal if necessary, and resubmit the proposal for public comment during the spring 2012 cycle.*

- **Affected Groups**
  Directors of Organ Procurement
  General Public
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators

Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Donor Family Members

- **Number of Potential Candidates Affected**
  In 2009, there were 920 DCD donors, an 8.5% increase between 2008 and 2009. In addition, some OPOs have up to 32% of their donors recovered as DCD donors. By clarifying the Model Elements, OPOs and transplant centers can increase the number of organs procured from DCD donations and ultimately increase the number of transplants, while at the same time providing improved safeguards involving the organ donation process.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The following two OPTN Strategic Goals and Priorities support the changes:
  - Maximum Capacity – The proposed changes will help to maximize the number of donors and transplants by identifying the currently unrealized donor potential through the clarification and updating of language.
  - Operational Effectiveness – The proposed changes will help to increase operational effectiveness by clarifying those elements required by OPOs, donor hospitals and transplant centers.

  Additionally, these changes more accurately reflect language in sections 121.8 (Allocation of Organs) and 121.9 (Designated Transplant Program Requirements) of the OPTN Final Rule.

- **Specific Requests for Comment**
  Please comment on what impact the following changes in terminology might have on your institution:
  - Changing “cardiac” death to “circulatory” death;
  - Withdrawal of “life sustaining measures” to “medical treatment/support”; and
  - The addition of the term “disease” which is included in the suitable candidate evaluation section.

Proposal to Update and Clarify Language in the DCD Model Elements

Affected/Proposed Bylaw: Attachment III to Appendix B of the OPTN Bylaws B

Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements do not change any current level of oversight by the donor hospital to ensure that appropriate practices are following for a patient's end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. The Committees changed the name Model Elements to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The Committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

Additionally, other policies that have the terms "Donation after Cardiac Death" will be modified for consistency. These proposed changes will help provide a common understanding of DCD protocols for the transplant community and the public.

Background and Significance of the Proposal:

In 2009, the OPTN Board of Directors charged the OPO Committee and Organ Availability Committee with the goal of reviewing DCD policies to determine if they were consistent with current practice. The Committees formed a joint Work Group and identified two areas that needed to be updated and clarified: 1) policy and bylaws and 2) definitions affecting DCD data reporting. Two subcommittees were formed to address issues for both areas; their work was approved by the Joint Work Group and ultimately approved by both committees.

The subcommittee spearheading the DCD policy review determined that existing policies were comprehensive; however, when they reviewed the DCD Model Elements that are included in the Bylaws, they concluded that the Bylaws were out of date and should be modified. The OPTN Bylaws require that OPOs and transplant centers incorporate the DCD Model Elements into their DCD policies.

The Committee is now seeking public comment on proposed changes to these Model Elements. The Committee recommends specific changes to update terminology such as changing the terms "Model Elements" to "Requirements." Additionally, the Committee agreed that the title "Donation after Cardiac Death" does not accurately reflect the Uniform Determination of Death Act's (UDDA) definition of death that states:

> "An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. (Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West Suppl. 1997)

With the definition in mind, the Committees propose that the name "Donation after Cardiac Death" (DCD) be changed to "Donation after Circulatory Death (DCD)" to accurately reflect the intent of the UDDA. This change is particularly important because the heart is not dead (nor are other organs) when the heart stops, but when circulation and oxygenation to the tissues are irreversibly stopped. Organizations such as the Society of Critical Care Medicine (SCCM) use this terminology. The OPO Committee and OAC unanimously supported this change.

The name "Donation after Cardiac Death" appears in seven policies (2.7, 2.8, 3.5.3.3, 3.5.5, 3.5.11.5.1, 6.4.2, and 6.4.3) and in sections I and II of Appendix B, Attachment III of the Bylaws. If approved, the terms "cardiac" will be changed to "circulatory" and "Model Elements" will be changed to "requirements" in those policies and Bylaws as well to promote consistency.

The phrase "withdraw life sustaining measures" was changed to "withdraw life sustaining medical treatment/support," to reflect current language used by the community, the Society of Critical Care Medicine, and CMS.

While rare, DCD donation may occur in patients that do not have a neurological injury, but a disease that renders them ventilator dependent (i.e. amyotrophic lateral sclerosis). As such, the term "disease" was included in the language that describes suitable candidate conditions. This change will be more specific in allowing these candidates to grant first person consent for donation and make these Model Elements more consistent with current practice.

Language was also added that reflects the CMS requirements to have a written agreement with participating hospitals. These changes are consistent with CMS expectations and make the Model Elements more complete and inclusive.

The Model Elements currently require an assessment to determine whether death is likely to occur (after withdrawal of life sustaining medical treatment/support) within a timeframe necessary for organ donation. This language was deleted because there is no industry standard that allows for a true assessment of the likelihood of death within a specific time frame. Each hospital establishes its own timeframe for organ acceptability.

Terms like "heparin" and "regitine" were changed to "anticoagulant and /or vasodilator administration" as this new language is less prescriptive in the event that there are newer or more appropriate medications to be used.

This proposal was first distributed for public comment during the March 11, 2011 to June 10, 2011 period. Prior to the Nov. 14-15, 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments. The Executive Committee directed the OPO Committee to review the comments outlined in the letters, revise the proposal if necessary, and resubmit the proposal for public comment during the Spring 2012 cycle. While reviewing the proposal it was discovered that some

of the language was incorrectly presented in the previous version of the document. This included some language that was deleted (shown with strikethroughs) that are not in the current bylaws. These mistakes have been corrected and the policy language included in this proposal shows all the changes to the bylaws with proposed new language underlined and proposed deletions with strikethroughs.

This proposal was distributed for public comment during the March 11, 2011 to June 10, 2011 period. Prior to the Nov. 14-15, 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments. The Executive Committee directed the OPO Committee to review the comments outlined in the letters, revise the proposal if necessary, and resubmit the proposal for public comment during the spring 2012 cycle. The OPO Committee reviewed the comments that expressed the following concerns:

- Provide an unmistakably clear markup document to show the entirety of the changes.
    - The OPO Committee modified the proposed language to address this concern. The new language is underlined and deleted language is identified by strikethroughs.
- Explicitly clarify the intent of the change from Model Elements to Requirements as to whether there is prescriptive intent that the language must be followed by OPOs and transplant hospitals without flexibility by locality.
    - The OPO Committee noted that upgrading the model elements to "requirements" is in accordance with the CMS regulations for OPOs and hospitals. This requirement makes it more protective for those patients involved. The requirement is designed to provide for flexibility depending on the state and local laws and regulations and the hospital specific policies and procedures.
- Eliminate any provision that prescribes that an OPO or transplant center provide DCD options to a conscious patient.
    - The OPO Committee noted that there have been cases when the OPO is contacted by the hospital when patients have irrecoverable, ventilator dependant, devastating neurologic injuries or illness and the patient is making the decision to withdraw the ventilator or cardiopulmonary assist device. This level of autonomy is consistent with the Federal Patient Self Determination Act of 1990[1]. In these cases, the OPO and hospital have a legal obligation to honor the patients advance directive which may include organ donation. Good end-of-life care would dictate that if the patient has questions or requests information regarding the donation process, then both the OPO and the hospital should cooperate to ensure that the patient receives the information required to make an informed decision.
- Develop and endorse recommendations for specific procedural safeguards for the application of DCD in conscious ventilator-dependent patients, to include psychiatric evaluation, a waiting period after the first patient request, and the requirement that a second patient request be made at the end of the waiting period. The proposed Requirements broaden donor criteria to include patients without cognitive neurological injury. As physicians, we are greatly concerned that patients with chronic illnesses such as spinal cord injury or amyotrophic lateral sclerosis (ALS) would be vulnerable to real or perceived pressure to decline further treatment in order to donate their organs, especially since the Requirements would permit evaluation of their eligibility for organ donation in advance of a decision whether to withdraw ventilatory or other life-sustaining support.

[1] Patient Self-Determination Act-Omnibus Budget Reconciliation Act of 1990. Pub L No. 101-508

- The OPO Committee agrees that these are important considerations for conscious patients making decisions to withdraw support and are advocates that hospitals should have appropriate procedures in place to assess the patient's mental capacity to make critical decisions for their own healthcare. Independent of the option for organ donation, these are hospital specific policies and procedures. The separation of the OPO and Hospital responsibilities related to these assessments further safeguards patient autonomy and decision-making.

- Eliminate any reference to ECMO or EISOR in the Proposal, and refer the many ethical and legal concerns raised by use of ECMO and EISOR in DCD practice to the OPTN/UNOS Ethics Committee for review and recommendation.
  - The OPO Committee noted that these were included as examples and were not endorsing the given use of these procedures. Instead the proposed requirements provide a safeguard for appropriate authorization in the case that these procedures are to be considered. Any of these procedures should be approved according to hospital policy. However, these examples have been removed from the proposal to eliminate any confusion.
- Eliminate any definition of death from the Proposal, as the definition of death is a matter of applicable state statutory or case law.
  - The OPO Committee agrees and the proposed requirements state that "death is declared in accordance with hospital policy and applicable state and local statues or regulation."
- Reconsider the traditional terminology of "Non-Heart-Beating Donation" as a clarifying designation for the practice in consideration.
  - The OPO Committee disagrees. The language has been changed to represent current clinical nomenclature.
- Explicitly endorse in the Proposal the longstanding ethical safeguard that the donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures has been agreed to by the patient's next of kin, as recommended by the Institute of Medicine. The proposed Requirements remove the important stipulation separating patient care from donation solicitations. Whereas previously the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate, under the proposed policy a patient may be evaluated as a DCD candidate *prior* to a decision by family members and caregivers, which ought to be free from external pressure. Gone is the crucial wall separating patient care from donation solicitations. Such undue influence on difficult decisions at a heart-wrenching time is ethically unacceptable.
  - The OPO Committee noted that the deleted language "the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate" in the original proposal was included then deleted during the drafting of the original proposed changes. That language has never been included in any version of the bylaws. The OPO Committee disagrees with the position that a patient may not be evaluated as a DCD candidate prior to a decision by family members and caregivers to withdraw life sustaining measures, or the position that a donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures have been agreed to. Under CMS regulation, hospitals are obligated to notify OPOs about "individuals whose death is imminent, or who have died" (CFR 42, Volume 3,Revised October 1, 2004, Chapter IV, Part 482: Sec.482.45). The timely referral of a potential

organ donor occurs prior to family knowledge of donation options for two primary purposes: 1) the evaluation of a patient as a potential organ donor can be facilitated without OPO communication with the family, and 2) the patient may have already been registered as an organ donor, which requires no further authorization by a surviving family or caregiver. By not allowing for an OPO's evaluation for donor candidacy prior to a decision to withdrawal, the health care system may expose families to the following misrepresentations: 1) to imply that their loved one is not a donor candidate, when in fact they might be a candidate; 2) to cause a delay in carrying out patient withdrawal procedures as agreed to by a surviving family, but prior to OPO involvement (The 2006 version of the UAGA allows for an OPO to "conduct any reasonable examination necessary to ensure the medical suitability." The UAGA has been enacted in 44 of 50 states and legislation pending in three states; www.nccusl.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006); 3) The surviving family may be lead to believe that they are authorized to make donation decisions for the individual at or near death, while in fact they may not be (all 50 states have passed legislation allowing for a first person authorization (FPA) for organ donation) and more than one hundred million persons are registered. The surviving family would not have access to information available through an OPO which is authorized to access FPA records.

The OPO Committee agrees that the ethical concerns and safeguards are paramount in the organ donation process. The changes to the model elements are intended to increase those patient protections and safeguards by ensuring that hospital have specific policies and procedures for donation after circulatory death. These proposed changes should serve to guide the process and ensure that each patient is treated with the dignity, respect and compassionate end-of-life care. These requirements serve to ensure hospitals and caregivers have a policy and to ensure that OPOs and Transplant Centers abide by the policies developed.

Collaboration:

The OPO and OAC Committees, as part of their annual goals, were tasked to review DCD policies and bylaws to determine if they are consistent with current practice.

- ***Collaboration:*** Before distributing the proposed changes for public comment, the Committees sought input from the following committees and transplant organizations:
    - Pediatric Committee
    - Thoracic Committee
    - Liver Committee
    - Kidney Committee
    - Transplant Administrators Committee
    - American Society of Transplantation (AST)
    - American Society of Transplant Surgeons (ASTS)
    - North American Transplant Coordinators Organization (NATCO)
    - Association of Organ Procurement Organizations (AOPO)

  Appropriate changes were made to the Model Elements based on recommendations that were received.

- ***Strengths and weaknesses:*** Strengths of the proposed changes:
    1. The language associated with DCD will be standardized.
    2. The language more accurately reflects the intent of the UDDA. The UDDA states that death occurs with the "irreversible cessation of circulatory and respiratory function." This language does not indicate that the heart is dead.
    3. Some of the changes incorporate CMS language requirements making OPTN Bylaws and CMS regulations compatible.
    4. The Committee believes that clarification of the language will promote better compliance.

    Weaknesses of the proposed changes:
    1. There may be some confusion over terminology once implemented.
    2. It is unknown at this time if transplant centers and OPOs will incur a financial burden because it is unknown how many resources will be needed to bring their protocols in line with the protocol requirements.
    3. Since there will be programming changes, the OPTN will incur costs.

- ***Description of intended and unintended consequences:*** The intended consequences for this proposal are that the community will have a clearer understanding of DCD requirements.

    An unintended consequence would be that each OPO and transplant center might incur a cost, as they will need to align their individual DCD protocols and policies with the new language in the Model Elements.

Supporting Evidence and /or Modeling:

The Committee comprises donor family representation and experts in the field of procurement and DCD and agreed that the changes reflect current practice.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

In 2009, there were 920 DCD cases reported in the United States. This number represents an 8.5% increase in the number of DCD cases reported nationwide compared to 2008, and indicates improved understanding of donor hospital willingness to develop DCD policies; OPOs to facilitate DCD protocols; and transplant centers to accept DCD organs to treat end-stage organ failure. Furthermore, with some of the more successful OPOs achieving up to 32% of their donor base as DCD donors, there exists a significant gap in unrealized donor potential that can be better captured by using more complete and up-to-date DCD Model Elements.

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

The following two long-range Strategic Goals and Priorities support these changes:

- Maximum Capacity – The proposed changes will help to maximize the number of donors and transplants by identifying the currently unrealized donor potential through the clarification and updating of language.
- Operational Effectiveness – The proposed changes will help to increase operational effectiveness by clarifying those elements required by OPOs, donor hospitals and transplant centers.

Additionally, these changes accurately reflect language in sections 121.8 (Allocation of Organs) and 121.9 (Designated Transplant Program Requirements) of the OPTN Final Rule.

Plan for Evaluating the Proposal:

One year after the revisions are implemented, the Committee will review all policy violations related to non-compliance with the DCD Model Elements. The Department of Evaluation and Quality (DEQ) will collect the data. In reviewing the data, the committees will consider the following questions:

- *Has there been a decrease in the number of policy violations as demonstrated by complaints of policy violations?*
- *Has there been an increase in the number of DCD donations since the implementation of these revised Model Elements?*

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal does not require any programming changes to any of the data collection forms in UNet^{sm} but will require programming to update the UNet^{sm} glossaries and Online Help Documentation, and glossaries found on the public websites. The following programming changes would be required:

- Online Help documentation in DonorNet® and Tiedi® will need to be modified to reflect the change from Donor after Cardiac Death (DCD) to Donor after Circulatory Death (DCD)
- Online Help documentation in DonorNet® and Tiedi® will need to be updated to define which donors could be classified as a DCD donor
- UNOS and OPTN web site glossaries will need to be updated to define Donor after Circulatory Declaration of Death (DCD)

Operationally, transplant centers and OPOs will have to review and revise their current DCD protocols to align them with these changes. They will need to review their protocols, ensure that all elements are included, and proceed through their institutional structure to make the appropriate changes. All individuals involved in the practice of DCD will need to understand the changes.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Transplant professionals within OPOs and Transplant Centers	Policy Notice is included with the monthly e-newsletter to members.	30 days after the board of directors approves the policy change.
System Notice	Transplant professionals within OPOs and Transplant Centers	Email	30 days before implementation and day of implementation
UNOS Update Article	Transplant professionals within OPOs and Transplant Centers	Print publication is mailed to members	Earliest issue after OPTN Board approves the policy change.
E-newsletter article	Transplant professionals within OPOs and Transplant Centers	Email	Several mentions in various e-newsletters beginning at least 3 months before OPOs and TX centers are required to implement the change.

Compliance Monitoring:

During on-site reviews, DEQ staff will require that OPOs and transplant centers sign an attestation to the existence of DCD protocols and verify knowledge of those protocols through staff interviews.

DEQ staff will request a corrective action plan if the OPO or transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy and Bylaw Proposal:

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

Attachment III to Appendix B of the OPTN Bylaws

~~Model Elements~~ Requirements for Controlled Donation after ~~DCD Recovery Protocols~~ Circulatory Death (DCD) Protocols

~~*Introduction:* Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.~~

~~The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices. The joint OPO Committee/MPSC Working Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.~~

Introduction: Donation after Circulatory Death (DCD) describes the organ recovery process that may occur when a death is defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statues or regulation. A DCD donor may also be called a non-heartbeating or asystolic donor.

These policies will help OPOs and transplant centers develop the necessary DCD protocols. These guidelines set the minimum requirements for DCD recovery but do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs and transplants centers.

A. Agreement

Each OPO must have a written agreement with hospitals that participate in DCD recovery. The participating hospital must be a Medicare and Medicaid participating hospital or a Critical Access Hospital as certified by Medicare. OPOs can only have DCD agreements with hospitals that have a ventilator and a functional operating room.

B. Protocols

OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential donors, organ recovery and organ placement in compliance with OPTN policy.

C. ~~A. Suitable~~ Candidate ~~Selection~~ Evaluation

The primary healthcare team and the local OPO must evaluate potential DCD donors to

determine if the potential DCD donor has a permanent and irreversible neurological injury, or disease which may allow for a planned withdrawal of life-sustaining medical treatment or ventilated support.

1. ~~A patient (from age newborn to the DSA's defined upper age limit, if applicable) who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for DCD.~~

2. ~~Other conditions that may lead to consideration of DCD eligibility include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.~~

3. ~~The decision to withdraw life sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart.~~

4. ~~The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO and the patient's primary health care team.~~ The OPO ~~determination of donor suitability~~ may also consult with the ~~include consultation from the~~ OPO Medical Director and Transplant Center teams that may be considering the ~~donor~~ organs for transplantation.

5. ~~An assessment should be made as to whether death is likely to occur (after the withdraw life sustaining measures) within a time frame that allows for organ donation.~~

D ~~B~~. ~~Consent/Approval~~ Authorization for DCD Recovery

For the purpose of obtaining authorization for a DCD recovery, "legal next of kin" can include any of the following:

1. the patient who consents to be an organ donor candidate
2. the next of kin as defined by state or local law
3. the designated health care agent

~~1.~~ The OPO must receive authorization from the legal next of kin for any procedures or drug administration to prepare the patient for DCD recovery. ~~The legal next of kin may elect to consent to 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.~~

~~2.~~ ~~Clearance from~~ If required by local law, the OPO must receive clearance from a medical examiner/coroner. ~~must be obtained when applicable.~~

~~3.~~ ~~There should be a plan for patient care if death does not occur~~ The OPO must ensure that the patient's hospital creates a plan for patient care in the event that death does not occur within the established timeframe as defined by hospital policy, after the withdrawal of life sustaining medical treatment or ventilated support. ~~measures.~~ This plan should include ~~logistics and~~ provisions for ~~continued~~ end of life care including immediate notification of the patient's next of kin. ~~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.~~

E. ~~C.~~ Withdrawal of Life Sustaining Medical Treatment/Support ~~Measures/Patient Management~~

Prior to hospital practitioners ~~Before~~ withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to:

1. Verify the patient's identification.
2. Determine the process and location for withdrawing life-sustaining treatment or ventilated support. Items to be considered may include endotracheal tube (ETT) removal or termination of blood pressure management medications.
3. Review the roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
4. Review the plan for patient care in the event that death does not occur within the established time period, as defined by hospital policy, after the withdrawal of life-sustaining medical treatment or ventilated support.

~~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 T~~t~~ransplant Center surgical team may ~~shall~~ be present for the withdrawal of life-sustaining ~~measures.~~ medical treatment or ventilated support.

~~3.~~ No member of the O~~o~~rgan R~~r~~ecovery team or OPO staff may guide or administer ~~participate in the guidance or administration of~~ palliative care, or declare ~~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 process.~~

F. ~~D.~~ Pronouncement of Death

~~1. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.~~

~~2. The method of declaring cardiac death must comply in all respects with the legal definition of death by an irreversible cessation of circulatory and respiratory functions **before** the pronouncement of death. ** / ***~~

The patient care provider who is authorized to declare death must not be a member of the OPO or the surgical recovery team. Circulatory Death is death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulations.

Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy.

G. ~~E.~~ Organ Recovery

~~1. Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.~~

The surgical recovery of organs may not be initiated until the patient is declared dead.

~~**F. Financial Considerations**~~

~~a. OPO policy to ensure no donation related charges are passed to the donor family.~~

Below is the policy language for those OPTN and UNOS Policies and Bylaws that will also need to be changed to be consistent with the changes proposed to the Model Elements. Only the section that includes information on DCD is included here to eliminate the need to have entire policies listed when only a small portion of the policy requires a change.

APPENDIX B TO BYLAWS
OPTN/UNOS
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

Donation After ~~Cardiac~~ Circulatory Death: OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements ~~d model elements~~ set forth in Attachment III.

II. Transplant Hospitals.

Donation After ~~Cardiac~~ Circulatory Death. Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the requirements ~~d model elements~~ set forth in Attachment III.

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

2.7 REMOVAL OF NON-RENAL ORGANS. When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after ~~cardiac~~ circulatory death (DCD) donors.

2.7.1 Multiple Abdominal Organ Procurement. It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.

2.8 In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the ~~standards of the~~ ~~DCD Model Elements~~ Requirements for Controlled Donation after ~~Cardiac~~ Circulatory Death ~~Recovery~~ (DCD) Protocols as adopted in the OPTN Bylaws, Appendix B, Attachment III.

3.5 ALLOCATION OF DECEASED KIDNEYS

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

3.5.5 **Payback Requirements**. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), ~~3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - 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~~ Circulatory 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~~ Circulatory 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~~ Circulatory Death donors shall be defined as follows: (1) A controlled Donation after ~~Cardiac~~ Circulatory Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during

procurement of the organs.

3.5.11.5 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after ~~Cardiac~~ Circulatory Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

POLICY 6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS

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 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 brain death or donation after ~~cardiac~~ circulatory 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~~ circulatory 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 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.