Exhibit A

Crosswalk Describing the Language Changes for the
"DCD Model Elements" and the "Proposed Changes in the Controlled DCD Guidelines"

The following table will assist you in identifying the changes made to the DCD Model Elements and their new location. The Summary of Changes highlights those changes that are substantive and not strictly editorial in nature. Language that has been substantially changed is underlined.

Section & Content Current Model Elements	New Content Heading with the Proposed Change to Requirements	Summary of Changes
	A- Agreement	A — This new language requires OPOs to have a written agreement with hospitals that participate in DCD recovery. This language is in keeping with CMS requirements.
	B - Protocols	B — This new language requires OPTN members to have established DCD protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential donors. This language is in keeping with CMS requirements.
A - Suitable Candidate Selection	C. - Candidate Evaluation	C 1 — Language has been inserted that clarifies that a patient who does not meet the neurologic criteria for death but has a disease that results in necessary life-sustaining treatment of ventilated support may be a suitable DCD candidate. C 2 – Language has been added to allow candidates with spinal cord injury (i.e. C 1 fracture), or candidates with neurologic disease (i.e. amyotrophic lateral sclerosis) or pulmonary disease (i.e. end-stage pulmonary fibrosis) to be DCD donors. C 5 — Language stating that an assessment should be made as to whether death is likely to occur within a time frame has been changed to, "Create a plan for patient care in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support. This plan should include provisions for continued end of life care.

B – Consent/Approval	D – Consent/Authorization	D — Examples of drugs and/or procedures (i.e. femoral line placement, ECMO, bronchoscopy, anticoagulants and vasodilators) are listed with clarification that this list is not exhaustive.
C – Withdrawal of Life Sustaining Measures/Patient Management	E – Withdrawal of Life Sustaining Medical Treatment/Support	E — Life Sustaining Measures has been changed to"Life Sustaining Medical Treatment/Support." E 1 — The original Model Elements recommended a "timeout" prior to the initiation of withdrawal of life sustaining measures; however, it is required in the new guidelines. This is to ensure that only appropriate representatives of the hospital and OPO are present in the area where medical treatment is withdrawn to ensure that there is no influence by the surgical recovery team regarding withdrawal of life sustaining medical treatment/support. E 4 — The team must review their plan in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment. C 5 —This content was edited and moved to D. (See section above).
D – Pronouncement of Death	F – Pronouncement of Death	F — Circulatory death is defined as an irreversible, permanent cessation of circulatory and respiratory functions.
E – Organ Recovery	G – Organ Recovery	G — Language edited.
F – Financial Considerations		This language was eliminated from the guideline.

~~**These DCD protocol "Model Elements" went into effect July 1, 2007.**~~

~~ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS~~

~~Model Elements for Controlled DCD Recovery 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.

Controlled* Donation after Cardiac Death Recovery Protocol Model Elements

A. Suitable Candidate Selection:

1. A patient (aged newborn to 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. OPO determination of donor suitability may include consultation from the OPO Medical Director and Transplant Center teams that may be considering donor organs for transplantation.
5. An assessment should be made as to whether death is likely to occur (after the withdrawal of life-sustaining measures) within a time frame that allows for organ donation.

B. **Consent/Approval**

1. 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 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 process.

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. ** / ***

E. Organ Recovery

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

F. Financial Considerations

1. OPO policy shall ensure that no donation related charges are passed to the donor family.

The following supporting information will be posted on the UNOS/OPTN website.

**** Maastricht Classification – Definition of Controlled DCD Donors***

DCD donors are grouped by the Maastricht classification (1995; amended 2003):

I Dead on arrival to hospital

II Unsuccessful resuscitation

III Awaiting cardiac arrest – In-Patient (w/d of support)

IV Cardiac arrest after brain-stem death

V Cardiac arrest in a hospital inpatient

Controlled DCD donors would include those outlined in classification III of the Maastricht criteria.

***** The Uniform Determination of Death Act:***

The National Conference of Commissioners on Uniform State Laws in 1980 formulated the Uniform Determination of Death Act (UDDA).

The UDDA states that: "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.

A determination of death must be made in accordance with accepted medical standards. This definition was approved by the American Medical Association in 1980 and by the American Bar Association in 1981. Today all fifty states and the District of Columbia follow the UDDA as a legal standard of death.

Sources:

- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death (Washington: Government Printing Office, 1981), p. 73.Uniform Determination of Death Act. 12 Uniform Laws Annotated 320 (1990 Supp).

How is irreversibility defined?

From the Report of a National Conference on Donation after Cardiac Death.
Am J Transplant. 2006 Feb; 6 (2):281-91.

Irreversibility is recognized by persistent cessation of function during an appropriate period of observation. Based on a cardiopulmonary criterion, DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function *will not resume spontaneously*. This meaning of "irreversibility" also has been called the "permanent" cessation of respiration and circulation.

If data show that auto-resuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.

In clinical situations in which death is expected, once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (auto-resuscitation) may be only a few minutes. Current data on auto-resuscitation indicate that the relevant event is cessation of circulation, not cessation of electrical activity.

When life-sustaining therapy is withdrawn, based on the limited data available (presented by Michael Devita at the National Conference), spontaneous circulation does not return after 2 minutes of cessation of circulation.

How is the permanent absence of circulation determined?

From the Report of a National Conference on Donation after Cardiac Death.

Cessation of functions is recognized by an appropriate clinical examination that reveals the absence of responsiveness, heart sounds, pulse and respiratory effort.

In applying the circulatory criterion of death in non-DCD circumstances, clinical examination alone may be sufficient to determine cessation of circulatory and respiratory functions. However, the urgent time constraints of DCD may require more definitive proof of cessation of these functions by the use of confirmatory tests.

Confirmatory tests (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital protocol to assure the family and the hospital professional staff that the patient is dead.

****** Other Important Determination of Death Resources***

1. Recommendations for non-heart-beating organ donation, A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, ***Critical Care Medicine 2001 Vol. 29, No. 9***, pp. 1826-1831.
2. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement, Institute of Medicine, December 1997.
3. Non-Heart-Beating Organ Transplantation: Practice and Protocols, Institute of Medicine, 2000.