VHA HANDBOOK 1102.07 Transmittal Sheet November 15, 2013

ORGAN DONATION AFTER CIRCULATORY DEATH (DCD)

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook establishes policy and procedures for organ donation after circulatory death (DCD).
- **2. SUMMARY OF CHANGES:** This is a new Handbook that defines the ethical and clinical parameters of donation after circulatory death.
- **3. RELATED ISSUES:** VHA Handbook 1101.03 and VHA Handbook 1004.01.
- **4. RESPONSIBLE OFFICE:** The National Surgery Office (10NC2) is responsible for the clinical contents of this Handbook, and the National Center for Ethics in Health Care (10P6) is responsible for the ethical content of this Handbook. Clinical questions may be referred to 202-461-7148. Ethics questions may be referred to 202-632-8457.
- **5. RECISSIONS:** None.
- **6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of November 2018.

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ORGAN DONATION AFTER CIRCULATORY DEATH (DCD)

1. PURPOSE: This Veterans Health Administration (VHA) Handbook establishes procedures to ensure that organ donation after circulatory death (DCD) is conducted in accordance with established ethical and clinical standards. **AUTHORITY:** 38 U.S.C. 7301(b). **NOTE:** Refer to VHA Handbook 1101.03 for additional requirements concerning organ, tissue, and eye donation.

2. BACKGROUND:

- a. DCD is unique in that organ procurement occurs only after voluntary withdrawal of lifesustaining treatments resulting in the circulatory death of the patient.
- b. The Joint Commission Standard on Transplant Safety (TS.01.01.01) requires a hospital to establish a written donation policy for organ procurement following circulatory death or provide an agreement with the local Organ Procurement Organization that addresses the hospital's justification for not providing this service.
- c. VA respects the right of patients to decide for themselves (or through an individual authorized by state law to act on their behalf) to make their organs available for donation following death after voluntary withdrawal of life-sustaining treatment. In order to ensure that the quality of the patient's end-of-life care is not compromised by the prospect or process of such organ procurement, practitioners must act in accordance with the ethical and clinical procedures established in this Handbook.
 - d. DCD requires two separate approvals before organs can be procured.
- (1) The first approval is the informed consent for an end-of-life treatment plan that involves withdrawal of life-sustaining treatment. Informed consent is provided by the patient or the patient's surrogate. The patient's surrogate for informed consent is defined in 38 CFR 17.32 and VHA Handbook 1004.01.
- (2) The second approval is the authorization for donation of the patient's organs after declaration of death. Authorization for organ donation is provided by the patient or by an individual authorized by state law to act on the patient's behalf. *NOTE:* The individual authorized by VA as the surrogate for informed consent may or may not be authorized by state law to make donation decisions on behalf of the patient.
- e. When organs are procured through DCD, it is best to discontinue life-sustaining treatment in the operating room (OR) so that organs can be removed immediately following the medical determination of circulatory death.
- f. To ensure against conflicts of interest that may compromise the end-of-life care of the patient, activities related to the procurement of organs and activities related to the withdrawal of life-sustaining treatment must be separated. The transplantation team must not participate in the informed consent process for the end-of-life treatment plan, management of the withdrawal of life-sustaining treatment, or the determination of circulatory death. The transplant team will only participate in organ procurement. The transplant team may be in the Operating Room suite but

must not be present in the Operating Room at the time of withdrawal of life-sustaining treatments or pronouncement of circulatory death.

g. In obtaining and determining authorization for organ donation, including DCD, VA staff must follow applicable state law.

3. **DEFINITIONS**:

- a. <u>Circulatory Death</u>: Circulatory death is defined as the irreversible cessation of circulatory and respiratory function. "Irreversible" means that function will not resume spontaneously and will not be restarted artificially. The criteria applied by clinicians for determination of death are established by state law, and must include a documented absence of circulation, apnea, and lack of responsiveness to verbal and tactile stimuli.
- b. <u>Donation after Circulatory Death</u>: Donation after Circulatory Death (DCD), also referred to as "Controlled DCD," is the voluntary decision of a patient (or an individual authorized by state law to make a donation decision on the patient's behalf) to donate the patient's organs following the death of the patient after voluntary removal of life-sustaining treatments. *NOTE:* This definition replaces the term and definition of "Donation after Cardiac Death" as identified in VHA Handbook 1101.03.
- c. <u>Organ Procurement Organization</u>: Organ Procurement Organization (OPO) refers to an organization that procures solid organs. An OPO must meet the applicable requirements of the Public Health Service Act (42 U.S.C. 273(b)(1)), and be certified or recertified by the Department of Health and Human Services (HHS).
- d. <u>Organ Procurement Organization Coordinator</u>: An OPO Coordinator is an OPO staff member who assists in the donor management, suitability determination, and family services coordination. This individual facilitates the donation authorization process, coordinates the surgical procurement, assumes immediate responsibility for the preservation and distribution of the organs to transplant centers according to guidelines established by United Network for Organ Sharing (UNOS). *NOTE:* The OPO Coordinator does not participate in the clinical management of the potential donor.
- e. <u>VA Medical Facility-designated Requestor or Liaison</u>: The VA Medical Facility-designated Requestor or Liaison is an identified VHA facility-based staff member who assists the OPO. *NOTE*: "Designated requestors" must complete a course offered and approved by the OPO that provides training in the methodology for approaching potential donor families.
- **4. SCOPE:** The quality of the patient's end-of-life care must not be compromised by the prospect or process of organ procurement in the context of DCD. Accordingly, organ procurement in the context of DCD must only occur at VHA medical facilities that have an active inpatient surgical program and that meet all of the criteria and procedures established in this Handbook.

5. CRITERIA FOR DCD:

- a. DCD is only to be considered as a pathway to procurement of those organs whose viability is compromised by prolonged ischemia and cannot be otherwise preserved. Procurement of tissues (e.g., corneas, cadaveric veins, bone grafts) that can be otherwise preserved cannot be the sole purpose for DCD.
- b. DCD is only to be considered when a patient does not meet the accepted neurological criteria for determination of brain death.
 - c. To be considered a candidate for DCD:
 - (1) The patient must have documented a desire to be an organ donor in accordance with:
- (a) State law (for example on a driver's license, in a will, or on an organ donor registry) or be designated as a donor by an individual authorized by state law to make a donation decision on the patient's behalf; and
- (b) Departement of Defense Directive (DOD) Number 6465.3, dated May 4, 2004, Organ and Tissue Donation; or subsequent guidance provided by the DOD for active duty patients in a VA medical facility. *NOTE:* A copy of DOD Directive 6465.3 can be located at http://www.dtic.mil/whs/directives/corres/pdf/646503p.pdf. DOD defines "next-of-kin" differently than VA defines "surrogate."
- (2) The patient must not have expressed a preference, either verbally or in writing, against donation of his or her organs subsequent to the documented desire to be an organ donor.
- (3) The patient (or valid surrogate acting on the patient's behalf) must have been fully informed by the attending physician of the patient's prognosis, condition, and treatment alternatives. The patient (or valid surrogate acting on the patient's behalf) must have consented to:
 - (a) An end-of-life treatment plan that involves withdrawal of life-sustaining treatment; and
- (b) Pre-mortem interventions required for the purpose of maintaining organ function, such as arterial lines and vasopressor administration.
- (4) The patient must have been determined by the treating physician to be in a condition where circulatory death is likely to occur within 2 hours after withdrawal of life-sustaining treatment. If circulatory death does not occur within 2 hours after withdrawal of life-sustaining treatment, donation must not take place and the patient must be transferred from the OR to a level of patient care deemed appropriate by the ICU attending (see paragraph. 10).
- (5) The patient must have been determined to be a medically suitable donor by the OPO Coordinator (see VHA Handbook 1101.03).

- d. A patient who does not have decision making capacity and who does not have a surrogate authorized under VHA policy to consent to the treatment plan, is not a candidate for DCD (see sections 10 and 11 below, VHA Handbook 1004.01, VHA Handbook 1101.03).
- e. A patient who has not documented a donation preference in accordance with state law and who does not have an individual authorized by state law to make decisions about organ donation on the patient's behalf is not a candidate for DCD.
- **6. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK DIRECTOR:** The Veterans Integrated Service Network (VISN) Director is responsible for ensuring that each medical facility has a policy in place regarding DCD no later than June 1, 2014.
- **7. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR:** The medical facility Director is responsible for:
- a. Establishing local policy regarding DCD that conforms to this Handbook and educating appropriate staff regarding its contents no later than June 1, 2014.
- (1) In order to offer DCD the medical facility must have an active inpatient surgical service and the staff and facilities to meet all the criteria and procedures established in this Handbook.
- (2) If the VA medical facility does not have an active inpatient surgical service or does not have the staff or facilities to meet all the criteria and procedures established in this Handbook, it cannot offer DCD. Facility leadership may also determine that there are other clear and compelling justifications for not offering DCD. Under either circumstance, the medical facility must issue local policy specifying that DCD will not be offered at the facility. In addition, such facilities must establish policy for determining criteria and procedures for transfer of a patient who chooses DCD to another facility with the resources and expertise to appropriately manage the patient's care and successfully complete procurement following DCD.
- b. Ensuring that the medical facility has an agreement with an OPO, as required by VHA Handbook 1101.03, Organ, Tissue, and Eye Donation Process.
- c. Ensuring that, if the VA medical facility has an active inpatient surgical program, an OR with appropriate staff and equipment is provided for performing recovery of major vital organs, tissue, and eyes.
- d. Ensuring that the procedure for organ procurement, cleaning of the body, and transfer to the morgue is conducted by the appropriate staff with respect and sensitivity to the deceased and the deceased's surrogates and family members.
- **8. RESPONSIBILITIES OF THE FACILITY CHIEF OF STAFF AND NURSE EXECUTIVE:** The facility Chief of Staff and Nurse Executive are responsible for ensuring that:

- a. Health care professionals who object in good faith to DCD on ethical or religious grounds, or as a matter of conscience, are not required to participate in DCD procedures.
- (1) Care of the patient is delegated to a willing health care provider of comparable skill and competency.
 - (2) Care of the patient is not disrupted during the transition to a new provider.
- b. No members of the organ recovery team or OPO staff participate in the donor's end-of-life care or decision to withdraw life-sustaining treatment, and that no members of the organ recovery team or OPO staff participate in, or are present for, the withdrawal of life-sustaining treatment or the declaration of death.
- 9. RESPONSIBILITIES OF THE MEDICAL DIRECTOR OF THE APPLICABLE INTENSIVE CARE UNIT: The Medical Director of the applicable Intensive Care Unit (ICU) is responsible for ensuring that an attending ICU physician is qualified to manage the patient's end-of-life care, including withdrawal of life-sustaining treatment according to the following criteria:
- a. The attending ICU physician must have no conflict of interest, including but not limited to current clinical responsibilities on the organ recovery team, transplant service, or any health care responsibilities to known or likely recipients of organs from the donor.
- b. The attending ICU physician is familiar with guidelines delineated in this Handbook for removal of life-sustaining treatment for patients who have chosen to donate organs after circulatory death.
- c. The attending ICU physician must have personal experience with withdrawal of life-sustaining treatments.
- d. The attending ICU physician must have knowledge of state law criteria for determination of death and knowledge of VA's criteria for diagnosing circulatory death in cases of DCD (see subpar. 10h).
- **10. RESPONSIBILITIES OF THE ATTENDING ICU PHYSICIAN:** The attending ICU physician is responsible for:
- a. Notifying the Medical Director of the applicable ICU and facility Chief of Staff that organ procurement after DCD is contemplated.
- b. Ensuring that the interest in procuring organs does not interfere with optimal patient management and that the health care team's primary responsibility is to care for the patient.
- c. Obtaining informed consent for the end-of-life treatment plan involving withdrawal of life-sustaining treatment. The informed consent process must conform to VHA Handbook 1004.01 and must:

- (1) Include information about the process of treatment withdrawal and the palliative measures that may be offered to comfort the patient at the end of life.
- (2) Be conducted prior to and independent of a detailed discussion of DCD with the patient (or individual authorized to make a donation decision on the patient's behalf).
 - (3) Be documented in the patient's electronic health record.
- d. Ensuring that the health care team addresses any needs for pastoral care or other supportive services for the patient, surrogate, or family.
- e. Ensuring that the OPO Coordinator or VA medical facility-designated Requestor is notified of the intent to withdraw life-sustaining treatment from the patient.
- f. Confirming that no members of the organ recovery team or OPO staff participate in the donor's end-of-life care or decision to withdraw life-sustaining treatment, and that no members of the organ recovery team or OPO staff participate in, or are present for, the withdrawal of life-sustaining treatment or the declaration of death.
- g. Managing the care of the patient, after the OPO Coordinator or VA medical facility-designated Requestor has obtained authorization for organ donation, to include:
- (1) Obtaining informed consent and performing any pre-mortem interventions for maintenance of organ function (e.g., femoral cannulas, administration of pharmacologic agents, such as regitine and heparin).
- (2) Deciding when to transfer the patient, and managing the transfer of the patient from the ICU to the OR.
 - (3) Coordinating the patient's care with appropriate ICU and OR staff during OR stay.
- (4) Ensuring that removal of life-sustaining treatment is performed in a manner that respects patient comfort, dignity, and rights.
- (5) Ensuring that no procedure is performed or medication is administered for the purpose of organ procurement if it causes discomfort or potentially hastens death.
- (6) Ensuring that during withdrawal of life-sustaining treatments, other treatments aimed at comfort are provided, as appropriate, and narcotics and sedatives are titrated to the patient's comfort needs.
- (7) Ensuring that all procurement teams are assembled and ready prior to beginning withdrawal procedures. A timeout is required prior to starting the withdrawal of life-sustaining measures. The timeout is to verify patient identification, the respective roles and responsibilities of the patient care team and procurement team personnel, and the plan for patient care in the event that death does not occur within 2 hours after the withdrawal of life-sustaining medical treatment.

- (8) Ensuring that no preparations for procurement take place before the patient is unconscious and unresponsive to noxious or painful stimuli.
 - (9) Approving initiation of skin preparation and draping.
- (10) Returning the patient to an environment where appropriate palliative care can be provided consistent with current and established palliative care policy as applicable, in the event that organ ischemia is prolonged and the organ procurement is cancelled by the responsible transplantation surgeon or organ procurement surgeon.
 - (11) Ensuring that no organs are procured until after death is declared.
- h. Determining death in accordance with applicable state law, and diagnosing death by cardiopulmonary criteria for the patient who has chosen DCD:
- (1) There must be absence of circulation documented either by absent pulse pressure (the pulse pressure must be zero) using an arterial catheter, or by echocardiogram showing absent cardiac contraction (the heart is not beating).
 - (2) The patient must be apneic based on absence of coordinated respiratory effort.
 - (3) The patient must be unresponsive to verbal and tactile stimuli.
- i. Ensuring the preceding three criteria are simultaneously satisfied, and the patient is observed to satisfy these criteria continuously for a minimum of 2 minutes. *NOTE:*Observation for more than 5 minutes is not recommended. The clinical definitions of cardiac arrest, such as the absence of a palpable pulse in a large artery (i.e., the carotid, femoral, or brachial artery) do not suffice for for the purpose of DCD.
 - j. Authorizing initiation of organ procurement after declaration of death.
 - k. Documenting these steps in the patient's health record.
- 11. RESPONSIBILITIES OF THE MEDICAL FACILITY-DESIGNATED REQUESTOR OR LIAISON: As determined in the facility's agreement with the OPO and organ donation protocol (see VHA Handbook 1101.03), the facility-designated Requestor or Liaison is responsible for:
- a. Notifying the attending ICU physician that a discussion about donation after circulatory death will be initiated with a medically suitable patient (or individual authorized by state law to make a donation decision on the patient's behalf).
- b. Conducting, as appropriate, a donation authorization discussion with the patient (or an individual authorized by state law to make a donation decision on the patient's behalf) about DCD. The donation authorization discussion must include the following elements:
 - (1) Information about the process of organ procurement.

- (2) That withdrawal of life-sustaining treatment may be completed in the OR.
- (3) That pre-mortem procedures may be required for the sole purpose of maintaining donor organ function; these include procedures such as placement of femoral cannulas and administration of pharmacologic agents (e.g., regitine or heparin).
- (4) That removal of life-sustaining treatment may not always lead to death in a short period of time.
 - (5) That organs will not be procured until after the patient is declared dead.
- (6) That organs may not be procured if certain problems occur as determined by the organ procurement surgeon or transplant surgeon.
 - (7) That death is determined in accordance with state law.
- (8) That in the absence of a patient's stated preference to donate, the authorization to donate can be withdrawn (by any appropriately authorized person) at any time prior to the earlier of:
 - (a) Initiation of invasive procedures on the recipient; or
 - (b) Initiation of the recovery procedures.
- (9) That withdrawal of authorization does not prejudice access to any future benefits for which the decedent's survivors are eligible. *NOTE:* OPO coordinators and requestors must not use pressure or coercion to obtain or maintain authorization.
- (10) Answering any questions asked by the patient or the individual authorized by state law to make a donation decision on the patient's behalf.
- c. Documenting the decision regarding donation after circulatory death in the patient's electronic health record. A copy of the donation authorization must be provided by the OPO to the VA medical facility to be included in the medical record.

12. REFERENCES:

- a. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.
- b. VHA Handbook 1101.03, Organ, Tissue, and Eye Donation Process, dated April 30, 2009.
- c. American Medical Association, Council on Ethical and Judicial Affairs. 2005. Policy E-2.157, Organ Donation After Cardiac Death. Available at http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_10a05.pdf.

- d. Bernat JL, D'Alessandro AM, Port FK, et al. Report of a National Conference on Donation after Cardiac Death. <u>American Journal of Transplantation</u>. 2006; 6(2):281-91. Available at
- $\underline{http://www.organ.org/v2/assets/documents/resources/Resources_ReportOfANationalConference.} \\ pdf.$
- e. DOD Directive Number 6465.3, Organ and Tissue Dpomation, May 4, 2004. Available at http://www.dtic.mil/whs/directives/corres/pdf/646503p.pdf.
- f. DuBois JM, Delmonico FL, D'Alessandro AM. When Organ Donors Are Still Patients: Is Premortem Use of Heparin Ethically Acceptable? <u>American Journal of Critical Care.</u> 2007;16(4):396-400. Available at http://ajcc.aacnjournals.org/content/16/4/396.full.
- g. The Joint Commission. Comprehensive Accreditation and Certification Manual. January 1, 2013, Standard TS.01.01.01.
- h. United Network for Organ Sharing (UNOC). Model Elements for Controlled DCD Recovery Protocols. UNOS Bylaws. Appendix B, Attachment III. March 23, 2007. Available at http://www.unos.org/docs/Appendix_B_AttachIII.pdf.

DONATION AFTER CIRCULATORY DEATH FLOW DIAGRAM - MAJOR STEPS

(For specific responsibilities, please refer to the Handbook)

or pa

• Attending Intensive Care Unit (ICU) physician discusses end-of-life treatment plan with the patient or patient's surrogate and obtains informed consent for withdrawal of life-sustaining treatment

2

• After informed consent for withdrawal of life-sustaining treatment has been obtained, attending ICU physician notifies Organ Procurement Organization (OPO) Coordinator or VA facility-designated requestor/liaison of the intent to withdraw life-sustaining treatment

3

• The OPO Coordinator or VA facility-designated requestor/liaison discusses organ donation with the patient or the individual authorized by state law to act on the patient's behalf and obtains written authorization for organ donation

4

• The OPO Coordinator arranges for the organ procurement team to arrive

5

• The attending ICU physician ensures that no preparations for organ procurement take place before the patient is unconscious and unresponsive to noxious or painful stimuli