I. OBJECTIVES

The purpose of this policy is to outline the process and procedures for patients wishing to donate organs after cardiac death. Principles of organ donation following cardiac death (ODCD) include:

A. The request for organ donation after cardiac death can be initiated by the patient or the patient’s family/surrogates at any time.

B. The health care team can initiate the request for ODCD only after the patient or family have decided to withdraw life sustaining interventions and the patient has been determined by the Living Legacy Foundation to be medically suitable to donate organs. Decisions concerning the treatment and management of patients (including the decision to withdraw life sustaining interventions) must be made separately and prior to discussions of ODCD. The goal is to assure as much as possible the absence of coercion in regard either to withdrawal of life sustaining interventions or ODCD.

C. Consideration of organ donation shall occur only after the patient, surrogate, or family and physicians have discussed plans to withdraw life sustaining interventions (See MEL-017, Establishing Goals of Care, Including Limiting or Withdrawing Life Sustaining Interventions). Donation may be an important option for the patient or their surrogates. However, harm can result if the issue of donation is inappropriately raised.

D. It is the health care professional's primary responsibility to optimize the patient's care and to act for the patient's benefit, including respect for autonomy. The process of removing life-sustaining therapies may be done when it is determined that the burdens outweigh the benefits, or that there is no benefit from the treatments. An important aim of this policy is that the objective to procure organs does not interfere with the patient's best interests.

E. This policy explicitly prohibits any intervention whose intention is to shorten the patient's life.

F. Utmost attention and caution shall be taken to protect the dignity and rights of donors.
G. Health care professionals shall not be required to participate in the procedures described below if such participation is against their personal, ethical, or religious beliefs (See ELR 610, Staff Requests Not to Participate in Patient Care).

H. The principal objectives of this policy are to:
1. Ensure that families of potential organ donors are given the option of organ donation.
2. Ensure that potential organ donors are identified.
3. Ensure that the option of organ donation is given in a consistent manner, is decoupled, and occurs in an appropriate setting.
4. Ensure ethical issues and pastoral and spiritual needs of all potential organ donor families are addressed. (JCAHO R1.1, R1.3.5, R1.2).

II. INDICATIONS FOR USE
A. This policy discusses activities related only to organ donation following cardiac death. Organ donation after brain death is detailed in policy MEL006.
B. This policy will be considered only after the patient, surrogate, or family has made a decision to withdraw life-sustaining therapies and when indications specified below apply.
C. This policy applies to patients with a severe acute irreversible central nervous system injury who do not meet the criteria for brain death and for whom the family or surrogates have decided to withdraw life-support. The degree of neurologic injury should in all cases necessitate the need for mechanical ventilation.
D. This policy MAY apply in rare clinical circumstance when a patient or family has elected to withdraw life support and the patient is without severe irreversible neurologic injury, but death is expected within 60 minutes. In all such cases, the attending physician, Organ Donor Council Chair or designee and an "Attending Physician Disease Expert" must concur that consideration of the patient for organ donation after cardiac death is appropriate. One of the following must also apply: 1) the patient has an advance directive that indicates their desire to be an organ donor, 2) the driver’s license indicates the patient’s desire to donate, 3) the family has raised the issue of organ donation, or 4) there is other objective durable evidence of the patient’s expressed desire to be an organ donor. All other safeguards and processes below still apply. Examples of clinical circumstances which may be appropriate include: 1) a patient with Amyotrophic Lateral Sclerosis, an advance directive declining mechanical ventilation, and a commitment to organ donation, 2) a patient awaiting transplantation with a ventricular assist device who is no longer a candidate for receiving a transplantation, who desires discontinuation of mechanical support and has expressed a desire to serve as an organ donor.
E. Appropriate candidates for organ donation consideration shall be limited to those patients on life-sustaining treatment who are likely to die within a few hours of withdrawal of therapy (e.g., patients who are ventilator dependent). Patients will be candidates for organ donation only if they are expected to die within 60 minutes after the withdrawal of support. While this is acknowledged as part of the protocol, perfect prediction of those patients who will die within 60 minutes is not possible. Thus, patients should be selected based on the best medical judgment that they will not survive beyond this time period after support has been withdrawn. In cases where the attending physician/internist is uncertain about the possibility of death within 60 minutes, weight should be given to the expressed importance of this option for the patient and/or their family.
### III. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advance Directive</td>
<td>A legal document and communication tool used to declare one’s healthcare decisions, name a healthcare agent and/or communicate one’s wishes regarding donation at the time of death. It is supported by the Maryland Anatomical Gift Act and the Healthcare Decision Act.</td>
</tr>
<tr>
<td>Appropriate Setting</td>
<td>A quiet private place where discussion of withdrawal of life-sustaining therapy and the options of organ donation can be offered in a sensitive manner with appropriate support personnel present</td>
</tr>
<tr>
<td>Attending Physician Disease Expert</td>
<td>A member of the active staff who is providing direct patient care. In some cases the patient may be cared for by both an attending intensivist and a primary specialty attending physician. Both attending physicians must be supportive of proceeding with ODCD, but the primary attending physician may discharge the responsibility of the process to the intensivist. If a patient or family has elected to withdraw support based on indicated preferences and the clinical factors and prognosis do not involve central nervous system injury, the patient may be considered for the ODCD protocol only with the agreement of the Organ Donor Council Chair, or as a Surrogate one of the Ethic’s Committee Co-chairs; and the assessment of an independent expert with board certification related to the underlying disease state. This disease expert individual is expected to provide a written prognosis (akin to the Neurological consultant) about the primary disease state and prognosis and whether the patient would be expected to survive 60 minutes after withdrawal of life support. This individual must not be involved in providing the direct current care of the patient, nor in transplantation.</td>
</tr>
<tr>
<td>Brain Death</td>
<td>The irreversible cessation of all brain functions, including brain stem function. For the process of brain death declaration refer to the policy on brain death (MEL005). Patients who are declared brain dead may donate organs and tissues. Organ donation from this group of patients is accepted and is detailed in the current Organ Donation after Brain Death Policy (MEL 006).</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>The complete and irreversible cessation of cardiac and respiratory function.</td>
</tr>
<tr>
<td>Decoupled Request</td>
<td>The process of decoupling is intended to separate any health care team-initiated discussions of grave prognosis or withdrawal of support, from discussions of organ donation. This separation minimizes conflict of interest between the two discussions and allows families time to understand information conveyed to them. Only if and after the surrogate decides to withdraw life-sustaining therapy does the possibility of ODCD exist and therefore, this protocol applies. In some circumstances, patients or families may inquire about the possibility of organ donation before they have made decisions regarding life sustaining interventions. In this and only this circumstance, can the health care team respond to their need by discussing organ donation before decisions about withdrawal of life sustaining interventions have been made. Irrespective of any potential for organ donation, every family must be allowed time to understand the nature of the patient’s disease or injury and the prognosis for recovery. They must be allowed time to consider and convey the patient's wishes under these circumstances to the health care team. At a separate discussion, the topic of organ donation may be addressed if the patient is medically suitable and Living Legacy personnel are present on site to assist in explaining the specific procedures involved in ODCD donation.</td>
</tr>
<tr>
<td><strong>Subject</strong></td>
<td><strong>Organ Donation Following Cardiac Death</strong></td>
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<td>-------------</td>
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| **Ethics Consultant** | Member of the JHH Ethics Service who is called to assess the integrity of the ODCD process and to assure that the ethical standards of this policy and the Johns Hopkins Hospital are upheld, with particular attention to the absence of coercion. See responsibilities on page below (beeper 410-283-6104) |
| **Family** | The surrogate or legal next-of-kin for the patient as defined by Maryland Law and the JHH Informed Consent Policy (MEL002). The “family”, for non-consent issues (i.e. attending the withdrawal of life sustaining therapy, etc.), may encompass additional persons who are related or have a close personal relationship to the patient. |
| **Family Advocate** | The Family Advocate is a chaplain who has received special training and approval from the Chair of the Donor Council and Director of Pastoral Care Department for the role of family advocate. The Family Advocate serves as a 24 hour dedicated resource to provide impartial emotional, spiritual and crisis intervention support to the family of any patient with severe neurological injury irrespective of the likelihood of subsequent organ donation. The Family Advocate (beeper 410-283-6000) is called for all patients at a Glasgow Coma Scale of 3 but may also be involved with any patient who may be a candidate for ODCD as requested by the medical care team. See responsibilities below and Appendix B. |
| **Organ Donation Following Cardiac Death (ODCD)** | 1. At the Johns Hopkins Hospital, organ donation has been possible previously only by patients who were declared brain dead and not by patients who suffered a cardiac death. However, patients who have cardiac death may be considered candidates for “Organ Donation Following Cardiac Death” (ODCD). The following organs may be donated for transplantation: Lungs, liver, kidneys, pancreas, and small bowel. The selection of which organs may be procured for transplantation is based upon a combination of: 
   a. Living Legacy’s assessment of the potential donor's age, medical history, and current hospital course, 
   b. the patient or family's wishes indicated on a donor card, advance directive or via discussion with the family. 

   The transplant team makes this decision after their review of Living Legacy’s assessment. |
| **Physician Qualified to Pronounce Brain Death** | An attending physician with the delineated privilege for brain death pronouncement. The physician has documented training in neurology, neurosurgery or critical care medicine and sufficient knowledge, skills and experience to interpret the clinical evidence which constitutes the criteria for brain death determination. See Brain Death, Determination of Death by Neurologic Criteria (MEL005.) |
| **Program Coordinator** | Hospital affiliated personnel supporting the organ donation process, education of hospital staff, data collection and monitoring of family and staff satisfaction with the organ donation process. This person may also serve as a family advocate. (beeper 410-283-6667) |
IV. RESPONSIBILITY

A. Attending Physician

1. In providing medical care (outside the scope of this protocol), the attending physician shall inform the family of the patient's grave prognosis, answer questions, and provide emotional support. The attending physician shall identify, interpret, and apply the patient’s advance directives if there is one. If a patient/family has elected to withdraw life-sustaining therapies, the attending physician of record may delegate to an attending intensivist or ICU fellow the end-of-life discussions, removal of life-sustaining therapies, comfort care orders, and may delegate to the on-site intensivist (or ICU fellow designee) the pronouncement of cardiac death. The responsibilities of the attending intensivist or designee are detailed in the following section.

2. If the patient is a candidate for the OCDC protocol, the physician or nurse shall notify the on-call family advocate (410-283-6000) of the potential donor situation.

3. The physician or nurse shall notify the Living Legacy Foundation using the Maryland Donor Referral Line (410-242-1173) of the potential donor.

4. The physician, nurse, or family advocate shall notify the Organ Donor Council Chair (410-283-3866) or Designee about the possibility of ODCD.

5. The attending physician involved in the direct management of the patient in the intensive care unit at the time of consideration of organ donation must not have a real or perceived conflict of interest in regard to organ transplantation. The most important conflict of interest occurs when the attending physician provides health care both to the potential organ donor and to potential recipients of the donated organs. Other conflicts of interest may include financial benefit. If a substantial conflict of interest exists, then the responsibility for discussing organ donation and participation in removal of life-sustaining therapies must be transferred to an attending physician who has no conflict of interest. A physician involved in transplant surgery should not be involved in the request for ODCD. The Ethics Service is available to assist if a conflict of interest issue arises. If the physician wishes to approach the family/surrogate about the potential for organ donation, they must do so with collaboration of the Living Legacy coordinator. In general, and to minimize any potential conflict of interest for the physician, the Living Legacy coordinator will conduct these discussions and should obtain consent for organ donation. The medical team must not convey any urgency to the discussions of organ donation and decisions regarding organ donation.

6. The attending physician will manage the patient's medical care and removal of life-sustaining treatments, unless they have transferred these responsibilities to the attending intensivist or fellow-designee.

7. The attending physician will collaborate with the Intensivist and Neurologist/disease specific expert to provide an assessment of the prognosis with regard to the expectation that cardiopulmonary failure leading to death will occur within one hour after life sustaining therapy including ventilatory support is withdrawn.

B. Attending Physician Disease Expert

1. Provide an independent assessment of the magnitude, irreversibility, and prognosis of the injury or disease.

2. Collaborate with the Attending Physician and Intensivist to provide a written assessment of the prognosis with regard to the expectation that cardiopulmonary failure leading to death will occur within one hour after sustaining therapy including ventilatory support is withdrawn.

C. Chair of Donor Council
1. Serves as resource to assist in determining if this policy is applicable in cases where patient or family has elected to withdraw support and patient’s illness does not include central nervous system injury.

D. Ethics Consultant (Beeper: 410-283-6104)
   1. The Ethics Consultant is responsible for assessing the integrity of the ODCD process and to assure that the ethical standards of this policy and the Johns Hopkins Hospital are upheld, with particular attention to the absence of coercion. The Ethics Service consultant is expected to:
      a. review the chart and
      b. speak to both the health care team and the patient's family to assess: knowledge about the process, the possibility of coercion, the family’s willingness to proceed, the family’s understanding of the likelihood of successful donation and the plans in place should donation not occur, and any perception of a conflict of interest.

2. The consultant should specifically assess whether the family has decided to withdraw life sustaining interventions on behalf of the patient’s interests and are willing to donate the patient’s organs after death. The Ethics Service consultant will document their assessment in the chart and will be given appropriate time to complete their assessment without exception.

3. The Ethics Service consultant may recommend that ODCD not proceed if the ethical principles of this policy and the Johns Hopkins Hospital have not been upheld. In such instances, this opinion should be discussed with the Chair of the Organ Donor Council before the recommendation is documented. Further consultation with the patient’s attending physician, and the Chairs of the Ethics Service may be necessary.

E. The Family Advocate (Beeper: 410-283-6000), (See Appendix B).
   1. The Family Advocate shall be called when the patient has reached a Glasgow Coma Score of 3 (see policy MEL006) or when a family has elected to withdraw life-sustaining therapies.
      a. The family advocate shall answer the page within 10 minutes and respond on-site within 60 minutes.
      b. The family advocate is responsible for paging the Ethics Service consultant as early in the ODCD process as possible so that the consultant has sufficient time to participate in the process. The family advocate shall inform the family that the Ethics Service consultant is part of the ODCD process, and that the family has the option to speak independently with the Ethics Service consultant if they desire.
      c. Serve as a 24 hour dedicated resource for the family.
      d. Interact with the family and any individuals the family designate as their advocate
      e. Provide emotional, spiritual and crisis support to the family
      f. Support the family when information is given by the medical staff
      g. Assist in communication and help to assure understanding of information from the medical team to the family and from the family to the medical team.
      h. Assess the family’s understanding of information shared and convey to the medical team the need and/or readiness for additional information.
      i. Ensure that the family is not coerced by faculty, staff, trainees, or students of JHMI or by staff of Living Legacy in any discussions of withdrawal of life support or organ donation.
      j. Ensure that the family is allowed to make a decision regarding organ donation
      k. Document the above process on the Donor Tracking Tool
      l. The Program Coordinator (beeper 410-283-6667) may serve as back-up if the family advocate has not been reached within 10 minutes of being paged (see MEL006).
F. ICU Physician Withdrawing Support
   1. Will review the informed consent procedure to ensure that discussion with the patient's surrogate has included:
      a. the JHH current policies regarding life-sustaining therapies
      b. the process of removal of life-sustaining therapy, including the identification of palliative care measures that can be initiated before the Living Legacy coordinator evaluates the patient (e.g., analgesia or other comfort measures), and those that are appropriately delayed until after the Living Legacy coordinator evaluates the patient (e.g. withdrawal of therapies that would result in the patient’s death).
      c. the process of organ procurement from donors following cardiac death
      d. that withdrawal of life-sustaining therapy will be completed in the operating room or induction room
      e. that while death is expected during or shortly after discontinuation of life-sustaining therapies, death may not always occur in the period of time allowed for organ procurement (60 minutes)
      f. that organs will not be procured until after the patient is declared dead
      g. that based on the medical judgment of the transplant surgeon, organs designated for donation may not be procured if certain problems occur (e.g., due to ischemic injury)
      h. that death will be certified in accordance with existing Maryland law; and
      i. that consent can be withdrawn at any time until the procurement of organs without cost or prejudice
   2. The physician withdrawing life-sustaining therapies is also responsible for:
      a. Answering any question the patient's family may have.
      b. Deciding when to initiate transfer of the patient to the OR.
      c. Managing the patient's care with the assistance of an ICU nurse in the OR or holding area.
      d. Informing the surgeon when it is acceptable to start surgical preparation of the patient's skin (see below)
      e. Certifying death. The physician certifying death must not be involved either in procuring organs or in the care of any of the transplant recipients if those recipients are known to the individual at the time of organ donation. Completion of the death certificate and death summary in the medical record is the responsibility of the primary clinical service.
      f. Appropriate medical record documentation of involvement in the above process.

G. Neurologist/Neurosurgeon
   1. Provide an independent assessment of the magnitude, irreversibility, and prognosis of the neurologic injury and disease.
   2. Collaborate with the Attending Physician and Intensivist to provide a written assessment of the prognosis with regard to the expectation that cardiopulmonary failure leading to death will occur within one hour after life sustaining therapy including ventilatory support is withdrawn.

H. Program Coordinator
   1. Serve as resource to assist care team with process coordination for a potential ODCD as needed
   2. Support of the organ donation process, education of hospital staff, data collection and monitoring of family and staff satisfaction with the organ donation process.
   3. Serve in Family Advocate role, as appropriate. (Pager 410-283-6667)
   4. Serve as a back-up if the family advocate has not been reached within 10 minutes of paged
I. Registered Nurse
   1. The registered nurse or physician shall notify the Maryland Donor Referral Line (410-242-1173) of the potential donor at the time of a decision to withdraw support.
   2. The registered nurse or physician shall notify the on-call family advocate (410) 283-6000 of the potential donor situation.
   3. Assess the family's understanding of the information.
   4. Communicate the family's understanding of the medical information to the physicians.
   5. Clarify information given by the physician.
   6. Answer the family's questions.
   7. Provide emotional support to the family.
   8. Continue to provide ongoing nursing care during transport and in the operating room until the time of death.
   9. Provide ongoing documentation of vital signs and medications on the vital signs flowsheet.

J. Living Legacy Coordinator
   1. Evaluate the medical suitability of the potential organ donor.
   2. In circumstances when the Living Legacy Coordinator is called to evaluate the donor before the family has been made aware of the possibility of ODCD, the evaluation should be done as quickly as possible. This is to assure that the potential for ODCD can be assessed while simultaneously not delaying the withdrawal of therapies that normally occurs shortly after a family’s decision has been made. The definition of “undue delay” should be agreed to on a case-by-case basis by discussion between the attending physician and the Living Legacy coordinator at the time the coordinator is called. In most situations, the delay should be less than 1 ½ hours. The avoidance of undue delay depends on the timeliness of the health care team’s call to the Living Legacy coordinator as well as the timeliness of the Living Legacy coordinator’s assessment.
   3. Explain brain death and heart beating donation; provide the family with details of the option of ODCD. This discussion must include an explanation of: 1) any drugs administrated prior to the declaration of death related to transplantation, 2) any procedures involved, such as the placement of central venous access lines or lymph node biopsy including risks and benefits, 3) the process of declaration of death and 4) the possibility that organ donation may not be performed if death does not occur within one hour of removal of life-sustaining therapies including mechanical ventilation and support.
   4. Inform the family that the patient must be transported to the operating room before life-sustaining therapies are withdrawn, and offer the family the option of being present in the operating room when life-sustaining therapy is withdrawn and death is pronounced. The family may be offered the option of visiting the operating room as part of their discussions about location of withdrawal care.
   5. Obtain formal written consent for organ donation and explain that the family may rescind their consent at any time before the organs have been procured. This process must include the items discussed above and must detail the possibility that organ donation may not be possible and may not be successful.
   6. Consult with the attending physician or intensivist designee regarding the ongoing care of the patient, and timing of withdrawal of life-sustaining therapy
   7. Arrange for the OR teams and discuss procedures in detail with OR staff including consideration of most appropriate room should family intend to be present for withdrawal.
   8. Coordinate organ allocation and distribution.
   9. Provide the hospital with follow-up information about each donation case.
V. PROCEDURE

A. Process of ODCD Consideration

1. Patients may be identified as indicated in the Indications of Use section. Patients are not considered for ODCD until the decision to withdraw life-sustaining therapies has occurred (except as outlined in II.4). This protocol assumes that:
   a. The physician/nurse shall notify the family advocate to provide family support
   b. The physician/nurse shall notify Living Legacy to evaluate the medical appropriateness of the patient as a potential candidate for organ donation
   c. The attending physician, intensivist, neurologist and/or disease expert and Living Legacy will collaborate with respect to appropriateness of the patient as an ODCD candidate
   d. The medical care team must develop a family communication plan (see below)
   e. The family advocate shall contact the Program Coordinator and Organ Donor Council Chair
   f. An Ethics Consult is obtained (pager: 3-6104)

B. Assessment at End-of-Life

1. If the family decides to withdraw life-sustaining therapies and if they have not initiated a discussion of the option of organ donation, the health care professionals caring for the patient should decide whether it is appropriate to initiate such a discussion with the family (after consultation with Living Legacy), and should develop a family communication plan.

C. Assessment of Suitability for Organ Donation after Cardiac Death

1. The health care team should consult with a Living Legacy coordinator (410-242-1173) to notify them of the possibility of ODCD and to determine suitability for organ, tissue and/or eye donation.
2. The Living Legacy coordinator(s) will respond on site within sixty minutes and will evaluate the patient for medical suitability for organ/tissue donation through review of the medical record. The bedside physical assessment of the patient may occur only after discussion of the family communication plan and the introduction of the Living Legacy coordinator to the family.
3. The family advocate shall be present for the discussion, provide emotional and spiritual support, and assist the family in understanding the information given by the physician, Living Legacy coordinator and registered nurse to ensure that the family comprehends and is not coerced in any discussions.
4. The registered nurse shall be present for the discussion as appropriate, clarify the information given by the physician, answer questions, and provide emotional support.
5. All discussions shall occur in an appropriate setting.
6. The Attending Physician shall collaborate with as many individuals as appropriate including: the Intensivist, the Neurologist/Neurosurgeon and/or the Attending Physician Disease Expert to provide an assessment of the prognosis with regard to the expectation that cardiopulmonary failure leading to death will occur within one hour after life sustaining therapy, including ventilatory support, is withdrawn.

D. Discussion regarding Donation/Consent

1. The physician will introduce the Living Legacy coordinator.
2. All discussions shall occur in an appropriate setting (defined above).
3. The Living Legacy coordinator in collaboration with the medical staff shall inform the family of their option to donate organs/tissues, answer questions, and address concerns in a sensitive manner.
4. The Living Legacy Coordinator shall discuss in detail the procedures involved in ODCD. Specifically, the Living Legacy Coordinator shall discuss the location in which withdrawal of care will occur and the family's wishes with respect to being present for this process. They shall collaborate with Family Advocate and other members of the care team to prepare the family for the event, and shall notify the family of the possibility that organ donation may not be possible.

5. The Living Legacy coordinator in collaboration with the physician staff shall obtain consent for any procedures done on a patient specifically related to organ/tissue donation prior to the declaration of death. This includes but is not limited to: the administration of any medications specifically intended for organ donation purposes (heparin) and not intended for the patient's benefit, lymph node recovery (for tissue typing) and central venous access for cooling.

6. The Living Legacy coordinator shall obtain formal consent for organ/tissue donation and medical/social history on the appropriate forms and provide documentation for the medical record. All previously noted items regarding the organ donation process must be discussed with the family during the consent process. In addition, the possibility that the patient might die prior to the organ donation procedures should be discussed with the family. Organ procurement may proceed only if the patient's surrogate agrees to organ donation upon death of the patient and signs the appropriate consent form. Consent for donation can be withdrawn at any time.

7. If the family elects to proceed with organ donation, the patient will be maintained on life-sustaining therapies for organ perfusion until the time of their withdrawal in the operating room.

8. The family will not be financially responsible for medical bills incurred after they decide to withdraw life-sustaining therapies and while they are considering the option of organ donation.

9. Patients who lack decision-making capacity and are without surrogates shall not be considered for organ donation after cardiac death.

10. Any members of the health care team who perceives an ethical problem are encouraged to contact the Ethics Service.

11. The patient's attending physician(s) must agree with the proposed procedure and note this in the chart. They may be present in the Operating Room (OR) if they desire.

E. Withdrawal of Life-Sustaining Therapies: Assessment and Planning

1. Ethics Assessment
   a. See section IV, Responsibilities of Ethics Service Consultant.

2. Conscious Patient Assessment
   a. In the absence of pre-disease or pre-admission documentation in the form of an advance directive stating a similar perspective, a formal psychiatric evaluation is required before proceeding.

3. Timing
   a. The family must be allowed adequate time to visit at the bedside, to grieve, to prepare for withdrawal of life-sustaining therapies and for the patient's expected death in order to facilitate the grieving process in the setting of their choice. This important part of the grieving process will not be compromised by the need to recover organs.

4. Location
a. Families may opt to be present in the operating room suite at the time of withdrawal of life sustaining therapies. This will be determined in advance discussion. Families will be prepared appropriately for the events should they wish to be present (including a visit to the operating room area if they desire).

5. Living Legacy assessment
a. The bedside physical assessment and ongoing evaluation and consultative management of the patient may occur after discussion of the family communication plan and the introduction of the Living Legacy coordinator to the family.

6. Physician Selection
a. The following criteria shall be used for selecting the supervising ICU staff physicians:
   • The physician must attend in an ICU or be the ICU fellow designee.
   • The physician must have familiarity with the guidelines on life-sustaining treatment and the policy for removal of life-sustaining support in potential ODCD.
   • The physician must have experience with withdrawal of life-sustaining therapies.
   • The physician shall have no clinical responsibilities on a transplantation service.
   • No physician who receives direct funding from a grant or industry involving the transplantation team shall be involved in the management of donors in the OR prior to declaration of death.
   • ICU physicians who have any other basis for conflicts of interest in individual cases shall decline or not be asked to participate in withdrawal of life support and certification of death.

F. Withdrawal of Life-Sustaining Therapies: Process Details
1. One of two possible scenario’s may occur: 1) the family may elect to not be present at the time of withdrawal of support or 2) the family may elect to be present in the induction room of the operating room at the time of withdrawal of support.
   a. If the family has decided to not be present, when the transplant recovery team is ready, the patient is moved to the operating suite accompanied by a physician and nurse. The nurse shall remain with the patient until the time of death. On arrival in the operating room, the patient is prepped and draped, all recovery materials and solutions are present. The surgical recovery team then leaves the room while the physician withdraws support. The physician will administer Heparin (300units/kg) at this time if the surrogate provided consent for heparin.
   b. If the family has decided to be present with the patient during withdrawal of life sustaining therapies, the withdrawal will take place in the induction room (or similar location) of the operating room. The OR coordinator should be contacted early in the process to arrange a suitable room. The patient will not be prepped and draped before the withdrawal. The family advocate will stay with the family until they are ready to leave. The family advocate will escort them from the operating room suite with OR and/or unit staff as needed, unless other arrangements have been made. The patient will be moved from the induction to the operating room after the family has said goodbye after death.
   c. The surgical staff responsible for organ procurement shall in no way participate in the removal of life-sustaining therapies. The surgical recovery team will not be present in the same physical location as the patient until certification of death, except for skin preparation and draping if the family has chosen not to be present.
   d. Anesthesiologists, who participate in the donor patient’s care, including withdrawal of life sustaining therapies, shall not be involved in the management of recipients of the donated organs. All equipment
(e.g., for assisted ventilation and monitoring) and drugs (e.g., sedatives and narcotics) shall be brought from the ICU. The anesthesiology staff may provide services such as assisting in connecting oxygen, compressed air, and suction equipment and providing technical support.

e. The administration of clinically appropriate medications as ordered by the ICU Attending Physician or Fellow designee, including narcotic and sedatives in appropriate doses to prevent discomfort is acceptable, with titration of medication based on signs compatible with distress. Patients with severe irreversible acute central nervous system injury should not be conscious or responsive to pain. Interventions intended to preserve organ function but which may cause discomfort to the patient or hasten death are prohibited.

f. If organ ischemia is prolonged (e.g., beyond one hour), it may not be possible to utilize organs designated for donation, and procurement may not be performed. The decision to cancel organ procurement because of prolonged ischemia rests with the responsible transplantation surgeon. Under these circumstances, the designated ICU physician may decide to transfer the patient to the ICU or previously arranged floor-bed.

g. No organs may be procured until death has been certified. To keep warm ischemia time to a minimum, other appropriate preparations for the procurement operation may take place prior to death. The staff of the Living Legacy or recovery team may perform skin preparation and draping as the specific family situation dictates.

h. The physician will proceed with withdrawal of life-sustaining therapies per patient/family wishes in the operating room suite designated for this purpose. The patient should be connected to functioning EKG leads. An arterial pressure wave form should be displayed at the time of withdrawal of life-sustaining therapies. If the patient appears to have pain or respiratory distress, the physician may order medication as part of his/her usual and customary practice if in the physician's judgment it is medically necessary. The physician is responsible for the ongoing management decisions of the patient until the declaration of death. This physician may not be involved as part of the transplant or procurement team. In a rare and unusual setting the burden of placing an arterial line may outweigh the benefits above. This clinical situation must be approved by the Organ Donor Council Chair or Ethics Service representative.

i. The physician will withdraw all ongoing life-sustaining therapies (except pain medications as above) including mechanical ventilation (i.e. extubate) and will observe the patient for the complete cessation of cardiac and respiratory function.

j. The possibility that death may not occur in the operating room should be discussed when consent for organ donation is obtained. Families should be informed that after discontinuing life-sustaining therapy if death does not occur within the allotted time when organ donation and subsequent successful transplantation will occur, the patient will be returned to the intensive care unit or a private room for ongoing palliative care. Respective shift coordinators responsible for floor bed management should be contacted at the time of organ donation consent in order that a suitable room is reserved to permit the family to remain with the patient should they survive to return from the OR. Every effort will be made to arrange for comfort and privacy.

G. Certification of Death
1. The physician certifying death must not be involved either in procuring organs or in the care of any of the transplant recipients if those recipients are known to the physician at the time of organ donation. Completion of the death certificate and death summary in the medical record is the responsibility of the primary clinical service.

2. For certification of death, the prompt and accurate diagnosis of cardiac arrest is extremely important. Procurement of organs cannot begin until the patient meets the cardiopulmonary criteria for death, that is, the irreversible cessation of cardiopulmonary function. The irreversible cessation of cardiac function is "recognized by persistent cessation of functions during an appropriate period of observation."

3. Because of concerns regarding conflict of interest, the criteria to be used in this policy is more stringent than the standard clinical practice for declaring death for patients who are not candidates for organ donation. (see Appendix A) 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 this purpose. The absence of a clinically palpable pulse does not necessarily mean cessation of mechanical activity of the heart.

4. The patient will be pronounced dead by the physician of record or intensivist designee after 5 minutes of absent circulation. The diagnosis of death by cardiopulmonary criteria requires confirmation of correct EKG lead placement and absent pulse via an arterial catheter (unless an exception is granted based on consultation between physician of record/intensivist designee and donor council chair. The pulse pressure must be zero, or by definition the heart is beating. In addition to pulselessness (as defined here), the patient must be apneic and unresponsive. Given the above, any one of the following electrocardiograph criteria will be sufficient for certification of death:
   a. 5 minutes of ventricular fibrillation
   b. 5 minutes of electrical asystole (i.e., no complexes, agonal baseline drift only)
   c. 5 minutes of pulseless electrical activity

H. Organ Recovery

1. Immediately after certification of death, organ procurement is to proceed according to standard procedures as directed by the transplant recovery surgeons and Living Legacy protocol.

2. The procedure for organ procurement, cleaning of the body, and transfer to the morgue is to be conducted with respect and sensitivity to the deceased and family. This is the responsibility of Living Legacy and JHH staff. A patient's family should be allowed the opportunity to view the body following organ donation if it is their wish to do so prior to transfer to the morgue.

3. Procured organs from donors following cardiac death shall be distributed in accordance with current JHH policies and United Network for Organ Sharing (UNOS) requirements.

4. Donor patients will not be charged for the costs of organ procurement (e.g., the use of the OR, special personnel, or medications used in the OR).

I. Post ODCD Follow-up

1. A committee composed of the chairperson of the Medical Ethics Service or designee, the Assistant Director of Nursing for OR Services or designee, and the Chief of Anesthesiology or designee may review all cases by request. A member of the Organ Donor Council and reviewers external to the hospital will be invited to observe these case reviews. The Organ Donor Council will receive summaries of any ODCD cases at least quarterly. The ethics consultant, ICU physician withdrawing life support, ICU nurse, and transplant surgeon or designee will be expected to provide a verbal or written report in whatever detail appropriate in order
that appropriate internal and external review of this protocol can occur. The physician withdrawing support and the ICU nurse will both sign the records indicating clinical observations and medications administered.

a. The purpose of this review is to:
   - assure that the above principles are followed
   - assure compliance with the above procedures
   - identify potential or actual problems and complications and recommend changes toward their solution;
   - protect the interests of the donor, recipients, the JHH, and involved health careworkers;
   - assess the effect of these procedures on the family's grief process to determine whether changes could be made to improve the process for donor families.

VI. REPORTABLE CONDITIONS

A. JHH Paging Operator: 410-955-5020
B. Maryland Donor Referral Line, Living Legacy Foundation (24 hours): Phone: 410-242-1173; Fax: 410-242-0771
C. JHH Ethics Consultant on-call: 410 283-6104 (pager)
D. Maryland State Anatomy Board (for total body donations - 24 hours): 410-547-1222
E. Program Coordinator (24 hours): 410-283-6667 (pager)
F. Family Advocate (24 hours): 410-283-6000 (pager)

VII. DOCUMENTATION

A. The physician shall document in detail any discussion with the family/surrogate regarding end-of-life discussions, including the option for organ and tissue donation. The death certificate must also include information regarding the request for organ and tissue donation. The specific points that must be included in the medical record are the documentation of:
   1. the patient's request to forego life-sustaining treatment by advance directive or family/surrogate discussion
   2. any request made for donation of organs or tissues
   3. any consent to donate organs or tissues
   4. whether a donation is made and accepted
   5. any objection to donation
   6. the reason for electing not to make a request for organ or tissue donation
B. The ICU Registered Nurse shall document vital signs, nursing treatment and assessments throughout End of Life Care. Medication dose, route, and timing will be documented on the vital signs sheet.
C. The Family Advocate shall document the above process in the medical record and on the Donor Tracking Tool
D. The Ethics Consultant shall document the results of their assessment.
E. The Living Legacy Coordinator shall complete appropriate forms and documentation regarding the formal consent for organ/tissue donation and medical/social history and provide documentation of consent for the medical record.

VIII. EDUCATION AND COMMUNICATION

This policy will be communicated to the appropriate JHHS personnel via the following channels:
1. Physician Education: Physician Advisors, Residency Training Coordinators, Department Chiefs and Medical Staff Newsletter.
2. Program Coordinator, in conjunction with Nurse Managers will be responsible for training nursing staff in all critical care units.
3. Living Legacy Staff and JHH Program Coordinator will provide training for clinical staff in the operating rooms.
4. Department management will be responsible for training appropriate staff.
5. Program Coordinator is available for questions at pager: 410-283-6667.
6. This policy will be placed in the Interdisciplinary Clinical Practice Manual on the JHH Intranet site http://www.insidehopkinsmedicine.org/hpo. Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.

IX. SUPPORTIVE INFORMATION

See Also:

The Johns Hopkins Hospital, Interdisciplinary Clinical Practice Manual
- Informed Consent Policy, MEL002
- Brain Death Policy, MEL005
- Organ Donation after Brain Death, MEL006

Living Legacy Foundation Policies and Procedures

References:
1. Department of Health and Human Services - Health Care Financing Administration [HCFA-3005-F]
2. Annotated Code of Maryland (Health General 14-510)
5. OPTN Bylaws DCD Model Elements for Controlled DCD Recovery Protocols July1, 2007

Sponsor:
- Medical Care Evaluation Committee
Organ Donation Following Cardiac Death

Developer:

- Organ Donor Council
- Vice President for Medical Affairs

**Review Cycle** - Three (3) years  
**Medical Board** - Approval Date 08/28/2012  
**Effective Date**: 09/27/2012

Vice President for Nursing & Patient Services  
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Date:______________________________________

Vice President for Medical Affairs  
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Date:______________________________________