


Name of Policy: <u>Organ, Tissue or Eye Donation after Death</u> Policy Number: 3364-100-45-03 Department: Hospital Administration Approving Officer: Chief Executive Officer - UTMC Responsible Agent: Chief of Staff Scope: The University of Toledo Medical Center and its Medical Staff	 Effective Date: September 1, 2019 Initial Effective Date: March 15, 1987		
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy		<input checked="" type="checkbox"/> Minor/technical revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy	

(A) Policy Statement

All patients have the right to elect organ donation in the event of death. This policy permits patients and families to consider organ procurement following both brain and cardiac (circulatory) death. Organ donation after cardiac (circulatory) death is defined as organ recovery from patients who are pronounced dead on the basis of irreversible cessation of circulatory and respiratory functions in accordance with accepted medical standards (cardiac death) and is intended to provide patients or families with an additional option of donation that complies with patient or authorized family directives after a patient or other authorized family member has chosen to remove life support in compliance with hospital policy.

(B) Purpose of Policy

The University of Toledo Medical Center’s (“UTMC”) philosophy is dedicated to providing the highest possible quality of care and to saving the life of the patient. When these efforts are unsuccessful and death is imminent, supporting the patient and members of the family is important. The purpose of this policy is to: outline the process for identification of potential donors and coordinate with the appropriate recovery agency (Life Connection of Ohio (LCO) or Community Tissue Services (CTS)); define a mechanism by which families of potential donors are offered the opportunity of organ, tissue or eye donation; and provide a formal mechanism by which UTMC may initiate the process of donation and to ensure that proper measures are taken and ethical issues are considered to protect the patient with regard to organ, tissue or eye donation and to carry out the wishes of the patient and the patient’s family.

(C) Procedure

The evaluation for a potential donor should be initiated when the patient meets the criteria outlined below to determine donor suitability. These patients will be referred to the appropriate recovery agency for determination of suitability for donation. There are two separate procedures outlined below for death by brain criteria and cardiopulmonary death criteria. Any physician opposed to organ donation may invoke the procedures for transfer of a patient where the patient or the family of the patient has requested to participate in organ donation. The Ethics Committee may be consulted on any issues involving donation and the appropriateness of procedures and processes. Capitalized terms have the meanings assigned to them at the end of this policy.

(D) Donor Suitability

The hospital will inform Life Connection of Ohio (LCO) through the Donor Referral line (1-888-262-5443) of all imminent deaths within 3 hours of the patient meeting the referral criteria listed below.

1. The patient has a devastating irreversible neurological illness or injury (traumatic, chemical, anoxia).
2. The patient has a heartbeat and is ventilated.
3. The patient has GCS of 5 or less, loss of 2 or more brain stem reflexes off sedation, brain death testing initiated or the patient, family or other authorized party is considering withholding or withdrawing life support and a formal DNR-CC order and form has been completed by medical staff and is included in patient’s chart. This decision is made entirely independently of and prior to discussion of organ donation initiated by UTMC or Life Connections of Ohio (LCO).

ORGAN DONATION PROCEDURE AFTER DETERMINATION OF DEATH BY BRAIN CRITERIA:

The process for organ procurement after determination of brain death is as follows:

1. Brain death protocol will be initiated by the attending physician, pursuant to policy 3364-100-45-02. If the patient meets the brain death criteria of this policy, the appropriate recovery agency will be contacted. Life Connection of Ohio (LCO) may be contacted through the Donor Referral line by dialing 1-888-262-5443. LCO will then contact the nurse and if appropriate, a Procurement Transplant Coordinator will be sent to do an on-site chart review for evaluation of donor suitability. LCO must be contacted before withdrawing or withholding life sustaining treatment. The nurse will advise the attending physician that LCO has been called.
2. The LCO Procurement Transplant Coordinator's evaluation at this stage should involve only a review of the medical record and not involve direct contact with the patient or family until after suitability for donation has been determined, unless the family has already initiated the discussion of suitability for donation.
3. The LCO Procurement Transplant Coordinator will discuss the possibility of organ and tissue procurement with the attending physician or the attending physician's designee.
4. If LCO determines that the patient may be a potential organ donor, the House Supervisor will be contacted by the staff nurse and advised that the patient is a potential donor determined by clinical indication for organ donation or death. The patient will not be exposed to any risk of potential harm, including drug treatment, solely for the purpose of organ procurement.
5. A family communication plan will be developed by the attending physician, nurse and Family Support Person. The physician, with the nurse and Family Support Person present, will explain the grave prognosis to the family, if not already explained. This will also include an explanation of brain death testing.
6. Upon completion of the brain death protocol the appropriate physician will inform the family of the results.
7. After the prognosis is given, the Family Support Person will remain with the family to provide support, reinforce the information and assess family understanding of the situation.
8. After the family has had time to comprehend and accept the information of brain death pronouncement, the Family Support Person will introduce the LCO Procurement Transplant Coordinator to the family, in the event the patient has been determined to be suitable for donation.
9. The LCO Procurement Transplant Coordinator will assess the family's understanding and acceptance of brain death.
10. Upon family acknowledgement of brain death, the LCO Procurement Transplant Coordinator and Family Support Person will offer the family the options for donation. Only a Designated Requestor may approach families of potential donors for the purpose of offering the option for donation.
11. If the patient's Designated Decision Maker decides against the donation, all further motion toward donation will cease, and upon pronouncement of death, the body will be handled in accordance with established hospital policy.
12. LCO will explain the complete donation process. If family declines to donate, LCO will withdraw from further activities. Patient and family will be given usual care and support.
13. If the patient's Designated Decision Maker agrees to the donation and there is no contrary indication by the patient, the LCO Procurement Transplant Coordinator will obtain the consent/authorization form, entitled Authorization for Anatomical Gift and have it signed by the Designated Decision Maker and the organ, tissue or eye donation recovery process will be initiated at the appropriate time. Management of the patient for organ donation will begin only after (1) authorization to organ donation has been properly obtained; (2) the patient's attending physician has confirmed death by brain criteria; and (3) the Coroner's office has given its permission to proceed.

14. If the cause of death falls within the Coroner's jurisdiction, the Coroner's office will be notified of the death at the time of pronouncement. If authorization for organ donation is obtained, the LCO Procurement Transplant Coordinator will then contact the Coroner's office to obtain permission to proceed with the donation process. The name of the individual in the Coroner's office granting permission and the date and time such permission was granted must be recorded in the patient's medical record by the individual obtaining the permission.
15. The LCO Procurement Transplant Coordinator will arrange for the surgical removal of the donated organs, tissues or eyes. According to Ohio law, the recovery of any organs, tissues or eyes for transplant must be coordinated by the federally designated organ procurement organization (i.e., Life Connection of Ohio), even if the organs, tissues or eye will be transplanted at UTMC. The patient's attending physician (or the attending physician's designee) will be responsible for the patient's care until the declaration of death and will be responsible for the termination and pronouncement of death. The organ recovery surgeon is responsible for the surgical recovery of the donated organs and will not be involved in the management of the donor before death is declared.
16. In the case of organ donation, the donor's body is transferred to the operating room with respiratory and circulatory support maintained.
17. The patient's attending physician (or the attending's physician designee) will record the date and time of pronouncement of death in the patient's medical record. Other relevant administrative procedures relating to death determination should be performed at this time.
18. Upon completion of the organ, tissue or eye removal, the donor's body is handled in accordance with established hospital policy.
19. The family of the patient will be emotionally supported by the Family Support Person, the attending physician (or the attending's physician designee) and hospital staff during the entire donation process.
20. All costs from the time that the family gives permission for donation until the donation occurs, or the patient is no longer a candidate for donation will be the responsibility of LCO.
21. Confidentiality of all donors and their families will be maintained. To the extent permitted under law, donor information will be released only to those parties associated with the donated organs, tissues or eyes and the involved transplant centers and eye/tissue banks.
22. LCO will send follow up letters to the donor family, and appropriate hospital staff and physicians regarding the disposition of the transplanted organs, tissues or eyes.
23. No intervention should be taken for organ donation purposes that could hasten death or cause suffering to the patient.

ORGAN DONATION PROCEDURE AFTER DETERMINATION OF DEATH BY CARDIOPULMONARY CRITERIA:

The following procedures pertain to patients for whom the decision has been made to withhold or withdraw life sustaining treatments. No consideration or discussion of organ donation will take place until after the decision has been made to withhold or withdraw life sustaining treatments unless this discussion of donation is initiated by the family. The transplant team will have no involvement in the decision to withhold or withdraw life sustaining treatments, or in determining whether organ donation is a possibility. The physician certifying death may not be involved as part of the transplant team. The process is as follows:

1. Prior to termination of life sustaining treatment, it should be documented that the patient does not meet criteria for brain death in the medical record. Only after a decision has been made to withhold or withdraw life sustaining treatments in compliance with hospital policy, will LCO be called. LCO will be called before any treatments are withheld or withdrawn in compliance with the Medicare and Medicaid Hospital Conditions of Participation. Hospital staff will contact LCO prior to terminating life-sustaining support for any patient who is of any age up to and including 70 years of age.
2. LCO will be called by the nurse and an LCO Procurement Transplant Coordinator will come on site to review the chart for evaluation of donor suitability. The patient's medical information will be reviewed by the Procurement Transplant Coordinator to determine donor acceptance or deferral. The LCO Procurement Transplant Coordinator's evaluation at this stage should only

involve a review of the medical record and not involve direct contact with the patient or family until after suitability for donation has been determined, unless the family has already initiated the discussion of donation.

3. The Procurement Transplant Coordinator will discuss the possibility of organ and tissue procurement with the attending physician or the attending's physician designee to verify that the decision to terminate life sustaining treatment has been made and to confirm that the potential donor is appropriate.
4. If LCO determines that the patient may be a potential organ donor, the House Supervisor will be contacted by the nurse and advised that the patient is a potential organ donor. If family declines to donate, LCO will withdraw from further activities. Patient and family will be given usual care and support.
5. If the patient is a potential donor, hospital staff or the LCO Procurement Transplant Coordinator will contact a UTMC Family Support Person. The family of the patient will be emotionally supported by the Family Support Person, the attending physician (or the attending's physician designee) and hospital staff during the entire donation process. A family communication plan will be developed by the attending physician, nurse, the LCO Procurement Transplant Coordinator and Family Support Person. The physician, with the nurse and Family Support Person present, will explain the grave prognosis to the family, if not already explained. During this time, the Family Support Person, nurse and attending physician will provide family support, reinforce the information, and assess family understanding of the situation. Hospital staff will comply with all applicable hospital policies involving the removal of life-sustaining support.
6. The attending physician, LCO Procurement Transplant Coordinator or a Designated Requestor will explain the complete donation process and the process for pronouncing death to the family and the process for donation by cardiac death, and the fact that the patient does not meet the brain death criteria. The LCO Procurement Transplant Coordinator will obtain informed written authorization for organ, tissue or eye donation from the Designated Decision Maker and ensure compliance with all other obligations under the Ohio Anatomical Gift Act, O.R.C Chapter 2108. The hospital may not proceed with organ donation if hospital staff is aware of any actual notice of contrary indications of the patient's or of the Designated Decision Maker.
7. The attending physician will be responsible for the following:
 - a. Reviewing the informed authorization procedure to ensure that it has included discussions with the patient or Designated Decision Maker of the following:
 - 1) hospital's current policies regarding patients for whom the goal of care is comfort measures only;
 - 2) the process of removal of life-sustaining treatment;
 - 3) the process of organ procurement from non-heart beating donors;
 - 4) that withdrawal of life sustaining treatment will be completed in the operating room or alternate area;
 - 5) that a femoral arterial catheter may be required;
 - 6) that while death is expected during or shortly after discontinuation of life support, removal of support may not always result in death of the patient in a very short time;
 - 7) that organs will not be procured until after the patient is declared dead;
 - 8) that death will be certified in accordance with Ohio law;
 - 9) based on the medical judgment of the transplant surgeons, that organs designated for donation may not be procured if certain problems occur (ischemic injury);
 - 10) that consent to organ donation may be withdrawn at any time without cost or prejudice; and,
 - 11) any other questions that the patient or 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 alternate area.
 - d. Informing the organ recovery surgeon when it is acceptable to start surgical preparation of the patient's skin.
 - e. Certifying death through completion of the death certificate and death summary in the medical record.

8. The attending nurse or LCO Procurement Transplant Coordinator will confirm that the county coroner/medical examiner has been contacted per hospital policy and procurement will proceed in cooperation with the coroner's office.
9. Laboratory studies or normalization of physiological parameters relevant to the donation process will only be started after signed family authorization is obtained and with the attending physician's order or the attending physician's designee's order. The patient will not be exposed to any risk of potential harm, including drug treatment, solely for the purpose of organ procurement.
 - a. Heparin may be administered only if only if it is determined that it will not hasten death or cause suffering to the patient.
10. Hospital's termination of life sustaining treatment protocol, policies or normal practices will be followed. A Do Not Resuscitate ("DNR") order will be entered into the patient's record in conformance with hospital policy. Once the decision is made to attempt organ donation after withdrawal of support, the process will accommodate the patient's Designated Decision Maker as much as possible within the guidelines of hospital policy. The patient will remain under the care of the attending physician until death has been pronounced. Life sustaining treatment will be withdrawn either in the intensive care unit, operating room or alternate area. In either situation, the attending physician or the attending physician's designee will carry out the withdrawal of support, continued care and pronouncement of death. If the Designated Decision Maker desires to have the family present, this can be accommodated in the operating suites area. Hospital policy will determine the number of family members that can be present in each of these locations.

If the Designated Decision Maker prefers to have their final moments with the patient prior to the withdrawal of support, then the patient will be moved to the operating room after the family has said their goodbye. The Designated Decision Maker should be informed that the latter situation will maximize the likelihood of successful organ donation. However, family comfort should outweigh the opportunity for successful organ donation.

11. Management of the patient for organ donation will begin only after:
 - a. Authorization for organ donation has been obtained from the patient or Designated Decision Maker;
 - b. The patient's attending physician has written the order for organ donor management; and
 - c. The Coroner's office has stated that it has no objection.
12. After suitability has been determined, authorization obtained and the Coroner has no objection, the organ recovery team is notified and assembled. When the organ recovery team, including the organ recovery surgeon(s) has arrived at the hospital, the patient is transferred to the operating room or alternate area while being mechanically ventilated and monitored. The surgical recovery team will prepare the skin and drape in a sterile fashion. Once the skin is prepared and all necessary recovery equipment and solutions are in place, removal of life support may then proceed in accordance with Hospital's policies and procedures under the direction of the attending physician or the attending physician's designee.
13. The family will be given the opportunity to spend time with the patient prior to the termination of supportive measures, as well as the opportunity to attend the withdrawal of support and death of their loved one.
14. The attending physician or the attending physician's designee will order the discontinuation of life support in conjunction with the organ procurement procedure.
15. The determination of death must be made by the attending physician or the attending physician's designee in accordance with accepted standards of care. A physician who participates in the procedures for removing or transplanting an organ will not be involved with the determination of death. The physician who pronounced the patient's death will document the date and time of death in the patient's medical record. Determination of death will be based upon either cardiopulmonary criteria or brain death criteria, whichever occurs first. Cardiopulmonary criteria includes a minimum of five (5) minutes of demonstrated breathlessness and pulselessness, five (5) minutes of palpable carotid or femoral pulselessness, dilated and fixed pupils and a failure to respond to painful stimuli such as sternal rub or finger pinch.
16. If the patient continues to breathe and has a sustained pulse and blood pressure for more than 120 minutes, or a time mutually agreed upon by the medical team and the OPO team, after discontinuation of life support, the donation process will not proceed and the family will be notified. The care of the patient will remain in the control of the attending physician.
17. Following pronouncement of death by the attending physician or physician designee, organ preservation solutions may be

administered and surgical recovery of organs will commence.

18. Upon completion of the organ removal, the patient's body will be handled in accordance with established hospital policy. The family will be given the opportunity to view the body after the recovery of organs has been completed.
19. All costs from the time that the family gives permission for donation until the donation occurs, or the patient is no longer a candidate for donation, will be the responsibility of LCO.
20. Confidentiality of all donors and their families will be maintained. Donor information will be released only to those parties associated with the donated organs, tissues or eyes as required by law.
21. LCO will send follow up letters to the donor family and appropriate hospital staff and physicians regarding the disposition of the transplanted organs.
22. No intervention should be taken for organ donation purposes that could hasten death or cause suffering to the patient. Attention will always be given to the comfort and dignity of the patient.

TISSUE/EYE DONATION

The evaluation of a potential donor following cardiopulmonary death will be determined by the following procedure:

1. A referral call will be made to the Donor Referral Line at 1-888-262-5443 within one (1) hour of cardiopulmonary death.
2. The Family Support Person will be notified by the nurse to provide support for the family and to assist in the donation process.
3. The initial call to the Donor Referral Line will determine initial suitability for tissue or eye donation. A second screening will be done during a second telephone call from a representative for the tissue or eye recovery agencies to assess final suitability and acceptance of the tissue or eye donor in accordance with the guidelines established by Community Tissue Services.
4. The representative from the tissue or eye recovery agencies will do a chart review with a hospital staff member over the telephone and may request parts of the record to be faxed to them.
5. Upon family's acknowledgement and acceptance of death the representative of the tissue or eye recovery agencies will discuss the options of donation with the Designated Decision Maker and request authorization for the donation process and autopsy consent, if applicable.
6. If the cause of death falls within the Coroner's jurisdiction, the time of death must be given to the Coroner's office by the hospital personnel upon pronouncement of death. If the family agrees to the donation process the representative of the tissue or eye recovery agencies will contact the Coroner's office.
7. If the patient's Designated Decision Maker agrees to the donation, the consent form, entitled Authorization for Anatomical Gift, will be signed by the Relative or the Guardian of the Decedent. If an autopsy is to be done an Autopsy or Post-Mortem permit must be signed by the Designated Decision Maker.
8. Hospital staff will be notified of the final acceptance or decline of the potential donor and final instructions given on the disposition of the body. The body must not be released from the hospital until this final notification is made by Community Tissue Services staff.
9. If the patient's Designated Decision Maker decides against donation, all further actions toward donation will cease and the body will be handled in accordance with established hospital policy.
10. Community Tissue Services or the appropriate recovery agency will send follow-up letters to the donor family.

(E) Definitions

“Organ” for purposes of donation under this policy refers to solid, vascular organs to include kidneys, heart, lungs, heart-lung, liver, pancreas, and small intestine.

“Tissue” for purposes of donation under this policy refers to cartilage, bone, heart valves, tendons, ligaments, and soft tissue (skin, fascia, dura).

“Designated Decision Maker” is the family member(s) that maintains authorization responsibility, for purpose of organ donation only. In descending order, the following persons may authorize donation absent indication to the contrary: spouse, adult child, parent, adult sibling, grandparent, guardian of person at time of death or identification as potential donor, any other person authorized or under obligation to dispose of the body. (ORC 2108.02)

“Designated Requestor” refers to an individual who has had specific training by LCO on the best practices for approaching families of potential organ, tissue or eye donors or training that has been approved by LCO.

“Death” refers to a patient being declared dead as determined by either brain criteria per policy 3364-100-45-02 or cardiopulmonary criteria

“Life Connection of Ohio” or “LCO” refers to the federally designated organ procurement organization for Northwest and West Central Ohio, which has Procurement Transplant Coordinators specially trained in assessing the suitability of potential donors, approaching the family and coordinating the recovery process with the appropriate transplant centers, eye banks and tissue banks.

“Procurement Transplant Coordinators” are those LCO agents who are specially trained in assessing the suitability of potential donors, approaching the family and coordinating the recovery process with the appropriate transplant centers, eye banks, and tissue banks.

“Family Support Person” refers to members from Pastoral Care Department of UTMC, who on a rotation basis will coordinate hospital staff in the process of approaching families of potential donors, act as family support and family advocate during the entire process, assess the understanding of the family and participate in the request for donation.

<p>Approved by:</p> <p><u>/s/</u> _____ <u>10/30/2019</u> Daniel Barbee, RN, BSN, MSA Chief Operating Officer Date</p> <p><u>/s/</u> _____ <u>11/08/2019</u> Samer Khouri, MD Chief of Staff Date</p> <p><i>Review/Revision Completed By:</i> HAS Legal Counsel Chief of Staff</p>	<p>Review/Revision Date:</p> <p>7/13/87 4/11/06 11/17/88 12/23/2009 5/10/89 4/23/2013 1/10/90 6/1/2013 3/13/91 5/1/2016 4/8/92 5/1/2017 6/9/93 9/1/2019 9/11/96 9/10/97 6/12/02 2/9/05</p> <p>Next Review Date: 9/1/2022</p>
<p>Policies Superseded by This Policy: 3364 100 45 03 Organ, Tissue or Eye Donation after Death</p>	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.