PURPOSE: To provide consistent guidelines to be followed in the support of organ, tissue, and eye donation for transplantation, therapy and research in accordance with Florida Statute.

POLICY STATEMENT:

1. Sarasota Memorial Health Care System (SMHCS) has entered into cooperative working relationships with LifeLink of Florida (LifeLink) and Lion’s Eye Institute for Transplant and Research (Lions Eye Bank) to identify potential organ and tissue donors.

2. All deaths, imminent deaths, and brain deaths will be referred to LifeLink of Florida as the federally designated organ procurement organization (OPO) for determination of medical suitability for organ/tissue donation. SMHCS has designated LifeLink Tissue Bank as the tissue recovery agency and Lion’s Eye Institute for Transplant and Research as the eye recovery agency. Cooperative agreements with the LifeLink/Lion’s Eye Bank are on file in the SMH Legal department. The policy is intended to be and will be interpreted to be consistent with Sections 765.520-765.547, Florida Statutes and all regulatory bodies including ACHA.

3. SMHCS recognizes the right of a person under Florida law to make an anatomical gift of all or part of his or her body by:

   a. Signing an organ and tissue donor card.
   b. Registering online with the donor registry.
   c. Signifying intent to donate on his or her driver’s license or identification card issued by the department. Revocation, suspension, expiration, or cancellation of the driver’s license or identification card does not invalidate the gift.
   d. Expressing a wish to donate in a living will or other advance directive or
   e. Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift.
If the decedent makes an anatomical gift by one of the methods listed above and in the absence of actual notice of contrary indications by the decedent, the document or entry in the donor registry is legally sufficient evidence of the decedent’s informed consent to donate an anatomical gift.

4. If the patient/decedent is medically suitable for donation, and the patient has not previously made a designation to make an anatomical organ or tissue donation, the option to make an anatomical organ or tissue donation will be offered to the legal next of kin by a LifeLink/Lions coordinator in accordance with applicable federal and state legislation.

5. All anatomical referrals and requests are to be documented in the patient’s medical record.

6. There will be no additional charges to the donor family for any procedures or supplies related to the donation process.

7. All information related to any donation will remain confidential except when written release of information is authorized.

8. The Transplant Procurement Team staff will be available 24 hours a day for the following responsibilities:
   a. Evaluation of the patient as a potential donor.
   b. Counseling with, and making request, of the family.
   c. Providing suggestions for donor management after brain death has been pronounced.
   d. Supplying a team to recover the organs, tissue, or eyes.
   e. Preservation and shipment of organs, tissue, or eyes.
   f. Education sessions as necessary to promote the proficiency of all persons responsible for compliance.

9. HIM will conduct an internal reconciliation of all procurements in accordance to policy 122.FD.01

EXCEPTIONS: As listed in the Procedure

DEFINITIONS: As listed in the Procedure

PROCEDURE:

1. Expired Patients And Imminent Death Patients
   a. The primary nurse or designee will call LifeLink/Lions at 1-800-64-DONOR (36667) or (813) 932-8808 on all patients who expire OR for all ventilated patients whose death is imminent or who have been or are about to be
declared brain dead regardless of age or diagnosis. The call shall be made to the OPO in a timely manner so that the OPO may evaluate the patient for medical suitability for organ donation, prior to deceleration of care, or termination of therapy. Timely referral for tissue or eye donations shall mean notice is given no later than one hour after cardio/respiratory death and prior to initiating release of body for transport outside the donor hospital.

b. The donor hospital shall provide a timely referral of all deaths and imminent deaths, regardless of age or diagnosis, occurring in the donor hospital. A timely referral should promptly be made to Lifelink once imminent death is determined.

For the purpose of organ donation, “imminent death” shall mean a situation in which a patient with severe, acute neurological injury/insult or ischemic event that requires mechanical ventilation is:

1) Being evaluated by a physician for a diagnosis of brain death;
2) Exhibits clinical findings consistent with a Glasgow Coma Scale less than or equal to five;
3) Being removed from a ventilator; and/or
4) Being considered for a palliative care consultation or withdrawal of any life sustaining therapies, medical or pharmacological.

c. Preliminary medical suitability is to be determined by LifeLink/Lions Eye Bank. A brief history of the patient may be requested by phone.

2. Organ Donation after Brain Death

a. The donor must meet the requirements of Brain Death Protocol Policy #01.MD.02. Physicians who are not members of the Transplant Procurement Team must make the declaration of death.

b. A representative from LifeLink will review the patient’s medical record and make a preliminary determination of medical suitability for donation.

c. Florida Medical law (FL Statute 406) requires deaths occurring under the following circumstances be investigated by the Medical Examiner:

- Criminal violence of any type
- Accidental deaths of any type
• Suicides
• Suddenly while in apparent good health
• Unattended by practicing physician or other recognized practitioner
• In police custody
• Suspicious or unusual circumstances
• Poisons
• By disease/injury or toxic agent resulting from employment
• By disease constituting a threat to public health.

d. When any death falls under the jurisdiction of the medical examiner, the hospital or recovery agency shall obtain a release from the medical examiner. This release will be documented on the patient’s chart. A patient who is an M.E. case is not excluded from being an organ donor however; the medical examiner’s decision is final.

e. If the decedent is medically suitable for donation, the option of organ and/or tissue donation will be offered to the legal next of kin by a LifeLink/Lions coordinator in accordance with applicable federal and state legislation.

f. A patient who has been declared brain dead who will become an organ donor will be discharged from the system and re-admitted under “Dr. LifeLink” as an observation patient. A new patient identification band will be applied with the patient’s new identification number.

   **Note:** The old patient identification band will remain in place.

g. A communication voicemail for notification of an organ donor will be sent to the liaison in Data Integrity at extension 8137.

If after being discharged from the system and re-admitted under “Dr. LifeLink”, LifeLink of Florida determines that organ procurement cannot occur the following process will be followed:

- LifeLink of Florida will be responsible to notify the patients’ family that organ procurement cannot occur.

- RN will enter a verbal order from the LifeLink Coordinator stating: unable to proceed with organ donation, family notified under a Patient General Order.

- SMH nursing staff will then proceed with postmortem care as outlined in SMH Policy 01.PAT.16 “Patient Expiration, Including Fetal Death, Pronouncing of Patient, Autopsy
3. **Donation after cardiac death (DCD)**

   The referral is made to LifeLink and the coordinator determines if the patient is a potential donor as outlined above in “Determination of Medical Suitability”. The donor must have an illness or injury that is reasonably expected to result in death within one hour of withdrawal of life support.

   a. After the family has decided to withdraw care and LifeLink determines that the patient is suitable for DCD donation, the LifeLink coordinator will discuss donation with the legal next-of-kin.

   b. Withdrawal of life support will occur in the operating room. An ICU nurse will provide patient care until the patient expires.

   c. Either the patient’s attending physician or physician’s designee will withdraw support. Pain management and other end-of-life comfort care will be prescribed by the treating physicians and administered by hospital staff, in the same manner that is used for non-donors who have life support withdrawn. No medication whose purpose is to hasten death will be given to the patient.

   d. For the purpose of donation after cardiac death, declaration will be based on observation of apnea, unresponsiveness to stimuli, pulselessness and asystole. All four criteria MUST persist for at least two minutes before death may be declared. The physician in charge, or his/her on-call physician, or two (2) RNs, must pronounce the patient dead.

   e. If there is prolonged cardio-respiratory function after discontinuation of life support and death is not declared within a period of time up to 90 minutes, efforts at organ retrieval will cease. In such cases, care of the patient will remain with the treating team. The patient will be returned to the unit from the OR.

4. **Patient Determined Ineligible for Organ Donation**

   If the patient is determined ineligible for organ donation at time of expiration, LifeLink will refer the case to Lions Eye Bank for consideration.

   a. **Tissue Donation:**
      1) A representative from LifeLink will contact the hospital by telephone to determine medical suitability.
2) If the patient is determined ineligible for tissue donation, LifeLink will refer the case to Lions Eye Bank for consideration.

b. Eye Donation:
   1) The Lions Eye Bank will contact the hospital by telephone to determine medical suitability.
   2) If the patient is determined ineligible for donation, Lions Eye Bank will communicate this to the morgue for body release.

c. After the family has made a decision about eye or tissue donation, LifeLink/Lions Eye Bank will communicate the decision to the Morgue (weekday 7:30am – 6 pm daily, after hours on voice mail at (941) 917-1186 to either hold the body for recovery or body release.

5. Documentation:

a. Hospital policy shall be followed for completing all forms required by the hospital (refer to SMH Policy #01.PAT.16 “Patient Expiration, Including Fetal Death, Pronouncing of Patient, Autopsy Requests, Post-Mortem Care and Medical Examiner Cases”).

b. Organ/Tissue/Eye Donation:
   1) If the authorized individual consents to donation, a consent form will be completed and medical/social history will be obtained by the LifeLink/Lions representative. A copy of the completed consent form will be filed in the patient’s medical record when organ and/or tissue recoveries are performed at the hospital.
   2) The patient’s label will be affixed to the page without concealing any other information.

c. If the authorized individual consents to donation via telephone, the consent form and/or the telephone tape recording will be kept on file at LifeLink or Lions Eye Bank. A copy of consent form will be provided to hospital to place in patient’s chart.

6. Recovery of Anatomical Gifts:

a. The recovery procedure will be documented in the patient’s medical record by the Transplant Procurement Team. Detailed procedure records are kept by LifeLink and can be obtained by calling 1-800-643-6667.

b. SMH policy and procedures for preparation of the body will be followed after the donation procedure.

c. When coming to the hospital for recovery of tissue and/or organs, transplant personnel may call the
Medical Records department and request the patient chart, if the chart is not available on the unit.

d. Organs and/or Tissues Recovery:
1) LifeLink coordinates the recovery process. LifeLink will coordinate and facilitate the surgical removal, preservation, and transportation of donated organs/tissue.
2) The Surgery department will be responsible for providing necessary personnel, equipment, and supplies to complete the vascular organ recovery. Anesthesia services will be provided by the hospital. LifeLink will provide qualified, credentialed, trained physicians and recovery personnel for the management and excision of organs and tissue from the donor hospital to an appropriate destination, on-site donor management, family consultation, and other aspects of recovery coordination.
3) LifeLink will place a copy of the Consent for Organ and Tissue Donation in the chart.
4) In the event the donor is to be released from the morgue for donation of tissue in Surgery, the morgue exit section of the Morgue Disposition Form will be completed. A new Morgue Disposition Form will be initiated upon the return of the donor to the morgue. Morgue personnel will handle release of donor from the morgue during normal duty hours and by security personnel after duty hours.

e. Eye Recovery: The Lions Eye Bank will coordinate the recovery and transportation of the donor eyes.

7. **Staff education:** Training is conducted upon hire, annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's Process Improvement program. Staff that may have contact or work with LifeLink/Lions must have appropriate training on donation issues including their duties and roles.

8. **Referral/medical record review:**

   a. In cooperation with SMHCS, LifeLink/Lions will review charts and/or death records, on all patients, on a routine basis to determine donation potential and/or compliance.

   b. All information will remain confidential during the review process and will not be publicly disclosed to any person or entity other than those persons or entities approved by the Donor Hospital or to medical providers for
diagnosis of organ or tissue donors or diagnosis or treatment of transplant patients, except as otherwise required by regulation or law. Such confidential information includes but is not limited to information on patients referred for vascular, tissue, and/or eye donation.

c. In collaboration with the OPO, SMHC collects data that measures the effectiveness of the organ procurement program. Referral and conversion rate information is collected and analyzed, and when possible, steps are taken to improve the rate.

RESPONSIBILITY:

1. Nursing Service: It will be the responsibility of the patient care directors to ensure that this procedure is followed.

2. Patient Financial Services (PFS): It is the responsibility of PFS to ensure that charges are appropriately billed. A copy of the hospital bill will be sent to LifeLink for audit purposes for separation of the charges. The separated charges will be returned to PFS by LifeLink within 30 days. Charges (i.e., tests, treatments,) that occur due to removal and/or the determination of suitability of organs will be billed to: LifeLink of Florida, 9661 Delaney Creek Boulevard Tampa, FL 33619.

3. Medical Examiner: It is the responsibility of the medical examiner and/or pathologist to perform his/her autopsy, and share the findings with the Transplant Procurement Team.

4. Transplant Procurement Team: The Transplant Procurement Team will assume full responsibility for assessment of medical suitability of potential donor, contacting donor families, and obtaining authorization/donor disclosure for donation, recovery, transportation, processing, placement, and shipping of all donated organs and/or tissues, as well as associated paperwork. The Transplant Procurement Team will notify the administrative supervisor on the off-shift and surgery (941-917-1253) when surgical services are required.
REFERENCE(S):
Florida Statute
Federal Regulation 482.45
Florida Statute
Federal Regulation 406
Sarasota Memorial Hospital Policy (01.MD.02) Brain Death Protocol for Adults. (11/1/12). SMH: Author.
Sarasota Memorial Hospital Policy. (01.PAT.16) Patient Expiration, Including Fetal Death, Pronouncing of Patient, Autopsy Requests, Post-Mortem Care and Medical Examiner Cases. (11/1/12). SMH: Author.
Sarasota Memorial Hospital Policy. (122.FD.01) Reconciliation of deceased patient list. (8/2017) Author Keeva Russell

AUTHOR(S):
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REVIEWING AUTHORS:
Dr. K.M. Hurwitz
Dr. Alan Brockhurst
DAC – Donor Advisory Committee

ATTACHMENT(S):
Checklist
APPROVALS:

<table>
<thead>
<tr>
<th>Signatures indicate approval of the new or reviewed/revised policy.</th>
<th>Date</th>
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<tr>
<td>Committees/Sections/Departments:</td>
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<tr>
<td>Donation Advisory Committee</td>
<td>10/4/2018</td>
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<tr>
<td>Catalina Jekonski</td>
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<tr>
<td>Critical Care Committee</td>
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<tr>
<td>Kenneth Hurwitz, MD.</td>
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<td>Medical Director Trauma Services</td>
<td>10/4/2018</td>
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<td>Alan Brockhurst, MD</td>
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<td>Sarasota County Public Hospital Board</td>
<td>10/15/2018</td>
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<tr>
<td>Quality Committee of the Board</td>
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<td>Director/Responsible Owner:</td>
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<tr>
<td>Sue Olsen, MSN, RN</td>
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<tr>
<td>Vice President/Executive Director:</td>
<td>10/8/2018</td>
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<tr>
<td>Connie Andersen, CNO</td>
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<tr>
<td>Chief of Medical Operations: (if clinical policy or appropriate)</td>
<td>10/11/2018</td>
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<tr>
<td>James V. Fiorica, M.D., CMO</td>
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<td>Chief of Staff: (if clinical policy or appropriate)</td>
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<td>Medical Executive Committee: (if clinical and review requested by CMO and COS)</td>
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<tr>
<td>Chief Executive Officer:</td>
<td>10/26/2018</td>
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<tr>
<td>David Verinder, CEO</td>
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Pre-Death/Pre-LifeLink:

Reminder: LifeLink does not assume care of patient until AFTER the patient has been pronounced. During the phase between consent for DCD and the patient’s death, LifeLink may ask for order management orders to be entered; you will need to obtain these orders from the Intensivist/Trauma Surgeon or Admitting/Attending as the LifeLink Coordinator requests.

1. Family wishes to withdraw life support; patient is not brain dead, may meet triggers for DCD
   - LifeLink contacted; physician speaking with family about prognosis, withdrawal of care.
   - LifeLink Coordinator on site; DCD discussed with family – family consent obtained
   - Two withdrawal of life support notes have been entered into SCM (CareVISION). [Reminder: notes must be written by attending/admitting and a consultant].
   - D.N.R. comfort measure order entered into SCM/CareVISION.
   - Withdrawal of Life Support Order Set entered into SCM/CareVISION.
   - Respiratory Therapist for pod and Respiratory Team Leader notified of plan for DCD.
   - Notify O.R. – provide early heads up of potential DCD patient.
   - Notify Intensivist/Trauma Surgeon of anticipated time to O.R.
   - Establish with family where the family wish to say their goodbyes.
   - Notify O.R. if family wishes are to be in the O.R. at time of death.
   - Medical Examiner notified if criteria met & documented in focus note.

Preparing the patient for the O.R.:

Prior to transporting the patient
   - Ensure that the LifeLink Coordinator has made sure that the O.R. is ready
   - Remove the comfort meds ordered for the patient from the Pyxis to take with you to the O.R.
   - Add IV extension tubing to the maintenance IV fluids infusing.
   - Ensure that R.T. knows the time that the patient is going to the O.R.

Transporting the Patient to the O.R.:

   - ICU RN’s & RT transport the patient to the O.R., via bed accompanied by the LifeLink Coordinator.
   - Cardiac monitor, O2 tank, ambu, ventilator, tough book laptop computer.
   - Expiration paper work and chart to O.R. with patient.
   - Reminder to ICU CN and HUC – keep current bed assignment for patient.
   - Notify Intensivist/Trauma Surgeon: patient on their way to O.R.
   - Assist O.R. team to position patient on the O.R. table.
   - Patient I.D. completed: time-out with O.R. staff.
   - Patient prepped and draped.
   - Heparin administered.
   - All LifeLink Team (Coordinators and Recovery Surgeons)
   - Patient extubated by R.T. (All DCD patients regardless of whether they are an ME Case or not will be extubated in the O.R., this is part of withdrawal of life care).
   - Discontinue all vasoactive infusions.
   - RN – provide comfort measures as needed, continue to monitor vital signs & document
   - If patient expires within 60 minutes of withdrawal of life-support; Pt. can be pronounced by 2 RN’s.
   - LifeLink team notified of expiration; notify ICU CN that patient has expired; ok to release room.
   - Expiration form completed by RN’s.
   - If patient does not expire within 90 minutes of withdrawal of life-support, return patient to his/her ICU room.
   - Family notified by LifeLink.