Organ, Tissue, and Eye Procurement Policy and Procedure

Purpose

To ensure that the family of each potential organ, tissue, and eye donor is informed of their option to donate and to encourage discretion and sensitivity with respect to circumstances, views, and beliefs of the patient and the patient's family.

In keeping with the Cleveland Clinic commitment to provide quality care, it is the practice of the Cleveland Clinic to work collaboratively with LifeBanc and the Cleveland Eye Bank to facilitate the donation process. LifeBanc is the Federally designated organ procurement agency of Northeast Ohio. The Cleveland Eye Bank is the Eye Bank Association of America certified eye bank serving Northeast Ohio.

Policy

Cleveland Clinic works to report all patient deaths and potential deaths by coordinating its efforts with its designated agencies. Every patient death is reported to the procurement agency in a timely manner. The procurement agency will be notified within one hour of cardiac cessation. Every potential death by neurological criteria is reported within three hours of agreed upon clinical triggers to the procurement agency. The procurement agency will be notified before withdrawal of all life-sustaining measures in any patient in the critical care area.

1. The call to the procurement agency to report a potential death by neurological criteria will take place when the following occurs.
   • A patient has a potentially life threatening brain injury, and
   • The Glasgow Coma Scale score is <5 and the patient has been maintained on ventilator support.
   In addition to the above, the following clinical trigger will be reported to the Cleveland Clinic Family Liaison within three hours of the event by Respiratory Therapy staff.
   • A patient with a cardiac arrest of >10 minutes with resumed circulation.

2. The call to the procurement agency to report a potential donation after cardiac death will take place when the following occurs.
   • The patient (if the patient has decision making capacity) or the Individual Legally Authorized to Withdraw Life-Sustaining Treatment (only if the patient lacks decision making capacity) with the treating physician has decided to discontinue life-sustaining interventions to provide comfort care for a patient with a terminal condition.
   • Prior to withdrawal of life-sustaining therapies.
Oversight and Responsibility

A. All designated clinical staff (Family Liaisons, physicians, residents, fellows, nurses) working in the hospital units are responsible for the notification process outlined in this policy.

B. LifeBanc and the Cleveland Eye Bank are responsible for the One Call for Life 24-hour Donor Referral Line 1-800-558-5433.

C. The ASC (Administrative Services Coordinator) is responsible for providing all the necessary paperwork for expiration to the Family Liaison. A call will be made to ASC on all deaths. ASC's will be responsible for paging the Family Liaison on-call.

D. The Donation/Transplantation Committee provides oversight for this policy/procedure and acts as an advisory group.

Procedure

I. Notification Process

A. The Family Liaison will be responsible for placing a call to the One Call for Life Donor Referral Line and documenting the Referral Number (provided by LifeBanc) in the Cleveland Clinic nursing notes or progress notes upon cardiac cessation, potential death by neurological criteria, or prior to withdrawal of life-sustaining therapies of every patient. Phone # 1-800-558-5433.

B. If the Family Liaison is not available to make the call for an imminent death, the following information may be called into LifeBanc by the clinical staff in the intensive care units:
   • Full name of the patient
   • Date of Birth
   • Social Security Number
   • Admission date and time
   • Admitting Diagnosis
   • Hospital Unit

C. Potential death by neurological criteria is to be reported within three hours of the following:
   • The patient has a potentially fatal brain injury.
   • The patient has a Glasgow Coma Scale of <5 and is being maintained on ventilator support.
   • The patient is post cardiac arrest for > than 10 minutes with sustained circulation.

   NOTE: Respiratory Therapy personnel report this to the Cleveland Clinic Family Liaison on-call.

D. Potential donation after cardiac death candidates will be reported within three hours after the decision to withdraw life-sustaining therapies has been made by the patient (if the patient has decision making capacity) or the Individual Legally Authorized to Withdraw Life-Sustaining Treatment,
with the physician, before the life-sustaining therapies have been withdrawn.

E. Expiration due to cardiac cessation is to be reported within one hour.

II. Request for Organ Donation- Death by Neurological Criteria (DNC)

A. If the patient is being hemodynamically maintained by mechanical ventilation and death by neurological criteria is imminent or the patient is pronounced dead by neurological criteria, the LifeBanc coordinator will discuss the case with the Family Liaison (or caller) and determine suitability or the need for an on-site evaluation.

B. If an on-site evaluation is completed, the LifeBanc representative will notify the Family Liaison of the potential for donation. A plan for offering the option of donation with the Individual Legally Authorized to Consent to Organ Donation will be discussed with the medical team members and will include a "best practice" approach for that individual. The "best practice" approach is

- Decoupling – the separation of death telling from discussion of donation.
- Making the request in a quiet private area.
- A joint request provided by a member of the procurement team and a member of the medical team.

C. LifeBanc checks the Ohio Donor Registry to verify donor status and will inform the Individual Legally Authorized to Consent to Organ Donation of the decedent's wish to be a donor as indicated by the Bureau of Motor Vehicles (BMV) designation. Alternatively, effective December 15, 2004, a decedent's wish to be a donor may be expressed in a State of Ohio Living Will Declaration. Or a LifeBanc designated requester, in conjunction with a member of the medical team, will discuss donation with the Individual Legally Authorized to Consent to Organ Donation if medical criteria are met as determined by the procurement agency.

D. In the event of a registered, consented donor listed on the Ohio Donor Registry after July 1, 2002 and the Individual Legally Authorized to Consent to Organ Donation is opposed to donation, or alternatively, in the event the patient elected to make an anatomical gift in a State of Ohio Living Will Declaration executed after December 15, 2004 and the Individual Legally Authorized to Consent to Organ Donation is opposed to donation, then The Cleveland Clinic Administrator on call will be notified immediately to assist as a facilitator in this event. The Cleveland Clinic Administrator on call may be reached through The Cleveland Clinic Operator.

E. A consent form will be completed by LifeBanc and a copy placed in the decedent's medical record for documentation of consent.
F. Final determination of recovery of organs, tissues, and/or eyes will be made only after the following
   • LifeBanc or Cleveland Eye Bank staff has obtained a hospital course summary from the Family Liaison and other hospital staff as needed.
   • LifeBanc has obtained a complete medical and social history from the Individual Legally Authorized to Consent to Organ Donation or other identified individual.
   • A thorough medical evaluation has been conducted.

G. If the Individual Legally Authorized to Consent to Organ Donation denies consent for donation (or donors who did not complete the Anatomical Gift section of a State of Ohio Living Will Declaration executed after December 15, 2004), the process is terminated. The ASC will be notified of the termination for release of the decedent by LifeBanc or The Cleveland Eye Bank.

III. Request for Organ Donation- Donation after Cardiac Death (DCD)

A. If the patient is being hemodynamically maintained and on mechanical ventilation, and the patient (if patient has decision making capacity) or the Individual Legally Authorized to Withdraw Life-Sustaining Treatment with the physician have decided to withdraw life-sustaining therapies to provide comfort care for a patient with a terminal condition, the LifeBanc coordinator will discuss the case with the Family Liaison (or caller) and determine suitability or the need for on-site evaluation.

B. If an on-site evaluation is completed, the LifeBanc representative will notify the Family Liaison of the potential for donation. A plan for offering the option of donation with the patient (if the patient has decision making capacity) and Individual Legally Authorized to Consent to Organ Donation will be discussed with the medical team members and will include a “best practice” approach. The “best practice” approach is
   • Decoupling – the separation of death telling from discussion of donation.
   • Making the request in a quiet private area or in the patient room if the patient is involved.
   • A joint request provided by a member of the procurement team and a member of the medical team.

C. A consent form will be completed by LifeBanc and a copy placed in the patient's medical record for documentation of consent.

D. Final determination of recovery of organs, tissues, and/or eyes will be made only after the following
• LifeBanc or Cleveland Eye Bank staff has obtained a hospital course summary from the Family Liaison and other hospital staff as needed.
• LifeBanc has obtained a complete medical and social history from the Individual Legally Authorized to Consent to Organ Donation or other identified individual.
• A thorough medical evaluation has been conducted.

E. If the patient or Individual Legally Authorized to Consent to Organ Donation denies consent for donation, the process is terminated. The ASC will be notified of the termination for release of the patient (once they are pronounced dead) by LifeBanc or The Cleveland Eye Bank.

Please Consult the Organ, Tissue, and Eye Donation after Cardiac Death (DCD) Procedure, Policy Number RI 105a.

IV. Request for Tissue Donation
A. If the decedent is deemed a suitable donor, the One Call for Life coordinator will obtain the phone number where the Individual Legally Authorized to Consent to Organ Donation can be reached at a later time (generally 1-2 hours after leaving the hospital). The Family Liaison can provide the information to the LifeBanc/Cleveland Eye Bank.
B. A consent form will be completed by LifeBanc/Cleveland Eye Bank via the telephone and will be faxed to Administrative Services or to the Family Liaison; a copy is placed in the decedent's medical record for documentation of consent -or- The Cleveland Eye Bank or LifeBanc may deliver a copy of the consent form to the hospital upon arrival for the recovery.
C. Final determination of recovery of tissues and/or eyes will be made only after the following have occurred.
• LifeBanc or Cleveland Eye Bank staff has obtained a hospital course summary from the Family Liaison
• A thorough evaluation has been conducted.
• A complete medical and social history from the Individual Legally Authorized to Consent to Organ Donation has been obtained.
• NOTE: In most cases, The Cleveland Eye Bank will complete this step after the recovery has occurred.
D. If the legal Individual Legally Authorized to Consent to Organ Donation denies consent for donation (or donors who did not complete the Anatomical Gift Section of a State of Ohio Living Will Declaration executed after December 15, 2004) the process is terminated and the Family Liaison is notified. The ASC will be notified of the termination for release of the decedent.
Definitions

Death by Neurological Criteria (DNC, formerly called Brain Death)
A patient who has sustained an injury to the brain sufficient that no part of his brain shows function on clinical testing, ventilatory apnea testing, and, if need be, ancillary testing. Patients declared dead by neurological criteria are legally considered dead even if they continue to have cardiac activity and are supported on a ventilator.

Donation after Cardiac Death (DCD)
In patients who sustain serious injury that leaves them in a terminal condition (as defined below), and in whom the patient (if the patient has decision making capacity) or the Individual Legally Authorized to Withdraw Life-Sustaining Treatment, with the physician, have decided to forgo life-sustaining therapies as a strategy to provide comfort, the prospect of organ donation can still be offered to the family. After withdrawal of life sustaining therapies and irreversible cessation of circulatory and respiratory functions, an eligible patient can be declared dead by cardiac criteria. Following the determination of death, organs can be recovered using the procedure for DCD.

Individual Legally Authorized to Consent to Organ Donation
Any of the following persons, or classes, in the order of priority stated:
- The spouse
- An adult son or daughter
- Either parent
- An adult brother or sister
- A grandparent
- A guardian of the person of the patient at the time of the patient's death
- Any other person authorized or under obligation to dispose of the body.

No donation can be made if the consent by a member of a class is opposed by a member of the same or a prior class.

1 This definition also applies to parents/legally authorized adult(s) donating the organs of minor children.

Individual Legally Authorized to Withdraw Life-Sustaining Treatment
Any of the following persons, or classes, in the order of priority stated:
- The guardian of the patient
- The Spouse
- An adult child. If more than one child, a majority of adult children who are available within a reasonable period of time to consult with patient's physician
- The patient's parents
- An adult sibling. If more than one adult sibling, a majority of adult siblings who are available within a reasonable period of time for such consultation
• The nearest adult (not described above) who is related to the patient by blood or adoption and who is available within a reasonable period of time for such consultation.

If an equal division in a priority class occurs, no consent can be given.

**Terminal Condition**
An irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a principal's attending physician and one other physician who has examined the principal, both of the following apply:
1. There can be no recovery.
2. Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

**Registered Donor**
An individual age 18 years or older, that has consented to the donation of organs, tissue or eyes and is registered with the Ohio Bureau of Motor Vehicles.

**Family Liaison**
A Cleveland Clinic employee who responds to the needs of families during a time of crisis and death. Family Liaisons assist clinical peers and Next-of Kin with all documentation pertaining to death. Family Liaisons may be reached by contacting the group pager at 28822.

**Cleveland Clinic Administrator on Call**
Assigned Cleveland Clinic employee by the Division of Nursing available for administrative issues. Contact pager # 21989 for assistance.

**Policy References**
Joint Commission LD.3.110
Senate Bill 188 Effective July 1, 2002;
Ohio Revised Code, Sections 2108.01-.12 and 2108.30; section 2133.01, 2133.07, 2133.08, and 2133.16.
The Ohio Donor Registry Brochure
Cleveland Clinic Policies
RI 105a - DCD Procedure Donation after Cardiac Death Protocol
#244 Organ, Tissue, Eye Donation; Registered Nurse Role
Post Mortem Care (Nursing Protocol p.5)
RI 106 Do Not Resuscitate Policy and Procedure
Ethics Policy: Policy on Forgoing Life-Sustaining or Death Prolonging Therapy.

**Issuing Office**
Quality and Patient Safety Institute

**Committee**
Donation Transplantation Committee
RI 105 2/2007 reviewed and approved by Cleveland Clinic Office of General Counsel and the Ethics Committee.

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