

ORGAN and TISSUE DONATION PROCESS

For DONOR REFERRALS and REPORTING OF DEATHS, call:

1-800-255-GIVE (4483)



MAKE a DONOR REFERRAL CALL within ONE HOUR of:
 GCS Equal To or Less Than 5 and Ventilator Dependent
 Brain Death Testing to be Initiated
 Prior to Withdrawal of Life Sustaining Therapies (Family Discussions = Early Referral)
REPORT a DEATH within ONE HOUR of:
 Upon Cardiac Death/Asystole



FOR IMMEDIATE NEUROLOGICAL DEATHS (ORGAN REFERRAL)

FOR CARDIAC DEATHS (TISSUE REFERRAL)

LIFE ALLIANCE
 ORGAN RECOVERY AGENCY
 UNIVERSITY OF MIAMI



Have available at the Time of Referral:
 Name, Age, DOB, Sex, Race, Height/Weight & MR #
 Admit Date, Time and Diagnosis
 Medical History such as Temps, Cultures, X-rays, Labs
Neurological Deaths ONLY: Current Neurological Status
Cardiac Death ONLY: Date and time of death or last known alive
 and two contact numbers where the family can be reached
 within a few hours after leaving hospital.

REMINDER: CMS & The Joint Commission (TJC) Compliance:
 Any Discussion of DONATION with families MUST be done in
 collaboration with the representatives of the donor programs
 for the hospital to remain compliant with CMS & TJC requirements.

UMTB
 UNIVERSITY OF MIAMI
 TISSUE BANK



Pre-Consent Collaboration with LAORA Staff

If after initial referral patient is determined to be a potential organ donor, the following **may** be requested on each shift:

- Vital signs & Current Fluid Maintenance
- Latest Lab Values
- Diagnostic Images (X-rays, CT, etc.)
- Supportive Medications
- Current Neurologic Status & Sedation (if any)

It is highly recommended that hospital staff engage in active Pre-Brain Death Donor Management to preserve organ viability and the option of organ donation for the patient and family, as follows:

- Maintain Blood Pressure over 100 mmHg systolic
- Optimize Oxygenation
- Treat Diabetes Insipidus (DI)
- Replace Fluids
- Treat active infections
- Maintain adequate urine output

Post-Consent Collaboration with LAORA

LAORA will collaborate with Hospital staff and conduct the consent approach. Upon obtaining consent for organ donation, the following **may** occur, but is not limited to:

Orders by LAORA in Collaboration with Hospital Staff:

- Optimize patient oxygenation
- Optimize hemodynamic parameters
- Hormone replacement, steroids, and antibiotics
- Bronchoscopy & Echocardiogram/EKG
- STAT labs every 4 - 6 hours
- ABO Blood Type X 2
- Hospital chart copies

Organ Placement

- OPO patient chart generated
- Electronic Recipient Lists generated
- Coordinate visiting organ recovery teams

Surgical Recovery in Collaboration with Hospital Staff (for patients not transported to UM facility)

- Anesthesiologist, Circulating RN, Scrub Technician
- Necessary equipment and instrumentation
- Procedure may last between 3-6 hours

Post Surgical Recovery

Life Alliance will notify pertinent parties upon completion of the surgical recovery to include Family/NOK, Medical Examiner (if applicable), Funeral Home, UM Tissue Bank (if applicable) and Eye Bank (if applicable).

If after initial referral patient is determined to be a potential donor, the following **may** be requested:

- Any known past medical history
- Labs & Diagnostics such as WBC, blood/sputum cultures, CT, MRI & X-rays w/ date, time & results
- SS# and/or Drivers License
- Fluids & Drugs Administered - including amounts, dates & times
- Nursing Notes
- EMS Runsheets - Legible
- ER Record (nursing notes, face & code sheets)
- History and Physical
- Status of ME & Physician signing Death Certificate to include contact for each
- General condition of body: Open wounds, decubiti, jaundice, edema, rashes, skin lesions, tattoos, piercings, & brandings
- If trauma: Extent of internal or external injuries, fractures, etc.
- Evidence of track marks, indication of IV drug use, etc.
- Active infections: viral, bacterial, fungal, and/or parasitic
- Hx of TB, Hepatitis, HIV, Cancer - when and treatment
- Temperatures for preceding 3 days IV fluids administered in last 3 hrs - amount and type
- Blood products administered in last 48 hrs - amount and type
- Was blood sample drawn at time of admit prior to administering blood and/or fluids?
- Current location of body: Time & Date place in Refrigerated Morgue
- Legal NOK: Name, relation, contact number(s), are they aware of death, whereabouts, their emotional state or demeanor
- Funeral Home information

Release of Body:

- Do not** release the body to funeral home until the outcome of approach is determined
- Outcome will be relayed to hospital

Donation Outcome:

- Consent Granted:** Hospital notified, transportation organized & consent provided to hospital
- Donation Declined:** Hospital notified and release body to the funeral home

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Federal Law (Center for Medicare and Medicaid Services (CMS) (1986) Conditions of Participation (COPs) 42 CFR 482.45) Requires that:

- ❖ ALL deaths & imminent deaths be reported to the local Organ Procurement Organization (OPO), and
- ❖ ALL families be given the option of donation at or near the time of death.

RELEASE OF MEDICAL RECORDS FOR DONOR SUITABILITY EVALUATION

Throughout the country hospitals are updating their agreements to comply with the privacy regulations contained in the Health Insurance Portability and Accountability Act (HIPAA). The core functions of an Organ Procurement Organization (OPO) or Tissue Bank are subject to two regulatory exemptions in the final HIPAA privacy regulations.

First, a health care provider may use or disclose information if necessary and as required by law. This exemption allows OPOs, Tissue Banks and hospitals to comply with the **Medicare Conditions of Participation, 42CFR § 482.45**

The second, and most broad exemption, is found at **§164.512(h)** which allows information to be released to organ procurement organizations or other entities involved in the procurement, banking or transplantation of a deceased donor's organs, eyes, or tissue for the purposes of facilitating organ, eye or tissue donation and transplantation. This allows the release of information by and to, donor hospitals, transplant hospitals, UNOS, tissue banks and laboratories.

Pursuant to these two exemptions, hospitals do not need to obtain patient consent for OPOs and Tissue Banks to do their core jobs; the coordination of donation and transplant, and the review of records. Furthermore, the Centers for Medicare and Medicaid Services' (CMS) responses to comments on the regulations clarify that OPOs are not 'business partners' of hospitals. The response states, in pertinent part: "...organ procurement organizations and tissue banks are generally not business associates of hospitals."

Thus, OPOs and Tissue Banks do not need to enter into "business partner agreements" with hospitals, unless they are acting in some other capacity. Finally, in the preamble to the final rule, CMS states that entities such as OPOs and Tissue Banks are not "health care providers" when they are engaged in the procurement or banking of organs, blood or tissues. Thus, with regard to hospital affiliations, OPOs and Tissue Banks are neither covered entities, nor business partners, and are specifically permitted to perform their core functions, with stringent confidentiality, but outside the ambit of HIPAA.

HHS REGULATIONS & HIPAA PRIVACY RULES

(Uses and Disclosure for Cadaveric Organ, Eye or Tissue Donation Purposes)

45 CFR 164.512 (h) Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes. A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

In Section 164.512(h) of the final rule, covered entities are permitted to disclose protected health information without individual authorization to organ procurement organizations or other entities engaged in the procurement, banking or transplantation of cadaveric organs, eyes, or tissue for donation and transplantation. This provision is intended to address situations in which an individual has not previously indicated whether he or she seeks to donate organs, eyes, or tissues (and therefore authorized release of protected health information for this purpose). In such situations, this provision is intended to allow covered entities to initiate contact with organ and tissue donation and transplantation organizations to facilitate transplantation of cadaveric organs, eyes and tissues.

ANATOMICAL GIFTS, FLORIDA STATUTE CHAPTER 765

Florida Statute 765.512 states that a gift of all or part of a body authorizes the decedent's medical provider, family, or third party to furnish medical records requested concerning the decedent's medical and social history. Once the gift has been made, the rights of the donee are paramount to the rights of others, except as provided by **s.765.517**.