Organ, Tissue and Eye Donation Guide for Funeral Homes
# Table of Contents

- **Introduction** ................................................. 3
- **About us** ................................................ 4
- **Tissue Donation Overview** ........................................... 8
- **Tissue Donation Process and Best Practices** ......................... 13
- **Organ Donation Overview** .......................................... 17
- **Organ Donation Process** ............................................ 20
- **Donation for Research and Education** ................................ 21
- **Reimbursement** ................................................ 24
- **Training Opportunities** ............................................. 25
- **Caring for the Donor Family** ......................................... 26
- **Funeral Advisory Board** ............................................. 27
- **Contact Information** ............................................. 28
Introduction

The availability of organs, tissue, and eyes for transplantation provides a source of life for ill, injured and dying Americans. Every year, tens of thousands of people are treated for life-threatening conditions with the gift of donated organs. Hundreds of thousands more benefit from healing and function-restoring transplants of donated tissues.

Donation and transplantation are processes involving many professionals, and no one is more important to this process than the funeral director/embalmer. You are the individuals who help the families of donors through their most painful period of grieving, and your involvement is essential to make the donation experience a positive one for family members and friends. The positive attitude you convey about donation will impact a family’s feelings about their decision to donate.

This manual is intended to assist you with the management of donors, services for donor families, and your interactions with hospitals, the San Diego Eye Bank, and other related agencies. Every effort will be made in the procurement process to minimize additional procedures on the part of the embalmer and to preserve as much of the circulation and natural appearance of the body as possible. In detailing procedures, we have provided an overview of the donation process as well as specific treatment information for the embalmer and funeral home.

Lifesharing recognizes the integral role of the funeral professional in the donation process, therefore it is our desire to support you in your efforts to serve the donor families. This guide is one of many resources and supports we wish to offer you.

“Lifesharing: A Donate Life Organization is committed to the life-saving and life-enhancing efforts of transplantation. We strive to be the leader in organ and tissue donation through education, collaboration and the provision of quality service.”
## About Us: Long-Time Partners

<table>
<thead>
<tr>
<th>Lifesharing</th>
<th>SDEB</th>
<th>UCSD Body Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Founded in 1984 as a division of UCSD Medical Center, Lifesharing is one of 58 regional non-profits dedicated to the life-saving and life-enhancing benefits of organ and tissue donation. As a federally-designated organization, Lifesharing provides organ and tissue recovery, donor family support, and educational services for the diverse population of approximately 3 million people in San Diego and Imperial Counties. Organ and tissue procurement services supply 28 donor hospitals and 4 local transplant centers with transplantable organs for the ever-growing waiting list of nearly 2,200 San Diego patients and more than 123,000 patients nationwide.</td>
<td>The San Diego Eye Bank is a non-profit corporation committed to the restoration and preservation of sight. It is the largest eye bank in California. Through our Gift of Sight program, they proudly have helped restore sight to over 25,000 individuals who suffered from corneal blindness as a result of disease or injury. They provide a full range of tissue distribution services and support for medical and basic research. In addition, they have established a state-of-the-art refractive laser center and sponsor a number of continuing medical education programs, among other services.</td>
<td>Each year, more than 1,000 Californians make an extraordinary gift to the University of California by donating their bodies to support the education of health professionals and to further scientific research. The UC San Diego School of Medicine recognizes the value of this unique gift and is committed to ensuring donors are treated with the utmost care and respect. Each year medical students hold a special memorial service to honor the donors. Family and friends of donors are welcome to attend.</td>
</tr>
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Who is Lifesharing?
Organ Procurement Organization & Tissue Bank

• We are proud to be affiliated with the UC San Diego Health System.
  » Two Departments:
    • Lifesharing: Federally Designated Organ Procurement Organization since 1987 (functioning since 1968)
    • Tissue Bank: Founded 1975
    • Employees of UC San Diego Health System

• We are a Non-Profit Organization.
• Official link between donors & those awaiting transplant.
Different Types of Donation

- **Organ Donation**: Hospital Deaths Only 1 day – 80 years of age
- **Tissue and Eye Donation**: Death occurs in or out of hospital. 1 day – 100 years of age Up to 24 hrs after death
- **Whole Body Donation**: Death occurs in or out of hospital Registration optional Post organ/tissue donation ok Some exclusionary criteria
Donation Process

1. Death occurs
2. Authorization is confirmed/obtained
3. Lifesharing is notified
4. Case is reviewed
5. Organs and Tissues are recovered
6. Organs are immediately sent to recipients
7. Tissues are processed and stored
8. Processed tissue is implanted up to 5 years later
What is a Tissue Bank

- Can be privately, publicly, OPO or University owned.
  - Tissue Recovery
  - Tissue Storage
  - Tissue Distribution
- Licensed by the state of California
- Registered and regulated by the FDA
- Accredited by the American Association of Tissue Banks (AATB)
- Eye Banks are accredited by the Eye Bank Association of America (EBAA)
What is Tissue Donation and what can be donated?

- Process of surgically recovering donated tissue for safe and sterile transplant into a recipient.

- During the donation procedures, the utmost care and respect is taken with the donor’s body.

- Tissue recipients do not have to be matched to their donors as rejection is not generally a concern.

- No age limit.
  » Lifesharing averages 440 donors annually/ over 30 per month
# Tissue & Eye Bank Assessment Checklist

To protect your Funeral Home and the families you work with, use this list to evaluate the quality of the tissue or eye bank who wishes to work with you. *If the answer to any of these items is “NO” or the tissue bank can’t provide the documentation, you must establish the level of risk to your Funeral Home and those people who may receive the tissues.*

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>Yes</th>
<th>No*</th>
<th>Documentation to Review</th>
</tr>
</thead>
</table>
| FDA Registration | | | □ FDA Registration  
□ Warning letters  
□ Most recent 483 |
| AATB Certification | | | □ AATB Certificate |
| Tissue Recovery Suite  
Does the Tissue Bank have their own Tissue Recovery Suite? | | | □ If the Tissue Bank requires space in the Funeral Home for Tissue Recovery you must establish the level of risk involved to your facility or the community with recovery of tissues at the Funeral Home. |
| Authorization/ Medical & Social History:  
Does the Tissue Bank take responsibility for completing the authorization form  
or Medical history with the family? | | | □ Copy of Authorization form  
□ Copy of Medical/Social History  
□ Does the Authorization form have all of the required elements listed in the attached FAQ.  
* funeral homes should never be responsible for obtaining authorization or history |
| Medical Record Review  
The Tissue Bank do a thorough medical record review? | | | Tissue Banks who do not review hospital medical records are putting your Funeral Home and the public at risk for tissue contamination. Avoidance of donors who die at hospitals is a questionable practice.  
□ Request the percentage of potential donors who were declined.  
* If Lifesharing or the San Diego Eye Bank declines a donor it is because the tissue is not suitable and could transmit disease. |
| Declines Donations when Appropriate  
Is the tissue donor decline rate about 30%? | | | □ Copy of tissue recovery standards specific to reducing contamination |
| Tissue Recovery Standards  
Does the Tissue Bank have policies and procedures to prevent contamination of the tissue? | | | □ Identification of Tissue Processors  
□ Discarded Tissue Policy  
□ Documentation of tissue recovered |
| Disposition of Tissue  
Does the Tissue Bank provide a comprehensive accounting for all of the tissues that are recovered? | | | □ Identification and approval process for Research tissue organizations  
□ Identification of for profit or not for profit status |
| Research Tissue  
Does the Tissue Bank provide a list of their approved Research Tissue organizations? See research tab. | | | |
| Education & Competency  
Documentation that their staff is trained and competent | | | □ Number of AATB certified staff  
□ Training documentation |
| Compensation  
Is compensation provided for the additional time and materials needed for preparation of the body? | | | □ Clear documentation of compensation practices |
Facts about Tissue Donation

• A single tissue donor can save and enhance up to 50 lives and touch countless more. The following tissues can be donated by one person:

  » Heart valves and conduits for 2-3 patients
  » Skin grafts for 4-6 patients
  » Bone grafts for 20-30+ patients
  » Tendon grafts for 8-10 patients
  » Vein grafts for 8-10 patients.
  » Corneas for two patients (Recovered by the San Diego Eye Bank)
Tissue Donation

Although less widely publicized than organ donation, tissue donation saves or enhances the lives of over a million people in the U.S. each year. Tissue can be donated upon one’s death to others in medical need.

HEART VALVES
Replace damaged or defective heart valves. Improves heart function.

SKIN
Grafts for burn victims, abdominal wall repair, breast reconstruction after mastectomy, rotator cuff repair. Promotes healing, reduces scarring, restores abdominal wall.

BLOOD VESSELS
Replace damaged arteries and veins. Increases circulation.

EYE
Replace diseased or damaged cornea, reinforce wall of the eye. Restores vision and prevents blindness.

BONE
Spinal fusion, reconstruction related to trauma, tumors, disease and fractures and fill defects. Restore mobility, decrease pain, prevent amputation and collapse of bone.

CONNECTIVE TISSUE
Repair facial deformity and resurface knee joint. Replacement and reconstruction of tendons. Restore appearance, mobility and decreases pain.
Tissue Donation Process

- Tissue & Eye Donation: 1 day > 100+ years of age
  - Death occurs
  - Donor referred to Lifesharing by Funeral Home, Hospital or MEO
    - 1-800-4-A-DONOR (1-800-423-6667)
  - Lifesharing/Eye Bank approach the family
    - Registry or Family Authorization
    - Extensive medical/social history and medical chart review
  - Body is transported to the Lifesharing Recovery Suite at the SD County Medical Examiner Office
  - Recovery takes place in an aseptic Operating Room using sterile techniques: within 24 hours after death
  - Tissues transported to tissue processors
  - Tissue grafts produced, packaged, stored and shipped to hospitals and dental offices.
Lifesharing Tissue Banking
Best Practices

• 40+ years in the community: University-based

• Partnerships:
  » Funeral Homes
  » Medical Examiner
  » Hospitals
  » Nursing Homes/Hospices
  » Tissue Processors
  » San Diego Eye Bank

• Not everyone can be a donor:
  » Only about 5% of our referrals become donors

• No “expanded criteria”:
  » FDA Regulations are the same for all tissue banks
  » Recipient Safety is most important

• Dedicated tissue recovery suite for 20 years
  » Hospital Surgical Suite Level Sterility
# Lifesharing Tissue Banking

## Best Practices

### Criteria and Best Practices for Reputable Tissue Banks and Eye Banks

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA Registered:</strong></td>
<td>Request the organization’s FDA registration, their last Inspection Report, form 483 (observation) and any warning letters that have been issued.   Lifesharing and San Diego Eye Bank, are both regulated by FDA and they received no form 483 or warning letters during their last site inspections.</td>
</tr>
<tr>
<td><strong>AATB Accredited:</strong></td>
<td>Accreditation by the American Association of Tissue Banks is voluntary and helps ensure that the Tissue Bank meets the highest standards.   Lifesharing is AATB accredited.  Their re-accreditation occurred in 2015 and re-accreditation occurs every three years. Lifesharing has been AATB accredited for more than 25 years.</td>
</tr>
<tr>
<td><strong>EBAA Accredited:</strong></td>
<td>Accreditation by the Eye Bank Association of America helps ensure that the Eye Bank meets the highest standards.   San Diego Eye Bank has been EBAA fully accredited for more than 30 years.</td>
</tr>
<tr>
<td><strong>California State Licensed:</strong></td>
<td>Request the organizations California Tissue Bank License. Lifesharing and the San Diego Eye Bank are both licensed tissue banks with the California Department of Public Health.</td>
</tr>
<tr>
<td><strong>Medical Record Review:</strong></td>
<td>In order to protect patient health information (PHI), the organization should gain authorization from decedent’s family to review the entire medical record of a decedent that has died in a hospital to determine medical suitability. Access of this PHI should be coordinated through a hospital’s Health Information Department. The organization should always provide a signed donor consent/authorization form when requesting release of medical records. Lifesharing and San Diego Eye Bank, provide the hospital with signed authorization, and in accordance with the MOU and HIPAA, properly accesses PHI and conduct this thorough medical record review to determine donor suitability.</td>
</tr>
</tbody>
</table>
| **Authorization (aka Consent):** | The organization uses a trained designated requestor (Family Services Coordinator) to gain authorization from donor families. Allowing a third-party who is NOT a trained designated requestor to gain authorization from a family can be detrimental. **Lack of coordination with Lifesharing and San Diego Eye Bank (1-888-4A-DONOR) creates a risk of a family being approached for donation by multiple organizations.** FDA, EBAA, CMS regulations and AATB standards require authorization. Lifesharing and San Diego Eye Bank, are your local hospital's contracted and trained designated requestors. The donation authorization process should include:  
  - Detailed information about the tissues and/or eyes recovered.  
  - The impact of the tissue and/or eye donation on funeral services and appearance of the body.  
  - Families must be given the option of declining the use of their loved one’s tissue for: Cosmetic purposes, International use, Use by “for profit” processors. |
| **Medical/Social History:**   | The organization obtains from the decedent’s family an accurate AATB and EBAA approved Medical/Social history. An essential safety element of tissue and eye donor screening and ultimately the determination of a deceased donor’s eligibility is the administration and completion of the Donor Risk Assessment interview (DRAI) questionnaire. Lifesharing and San Diego Eye Bank, uses the DRAI. DRAI is a National industry standard for AOPO, AATB, EBAA. |
| **Declines Donation when appropriate:** | To protect public health and safety, some referred tissue and eye donors are declined due to unacceptable medical/social findings. In order to provide safe, transplantable tissue, Lifesharing and San Diego Eye Bank uses AATB, EBAA & FDA standards to determine donor suitability and declines recovery when the decedent does not meet these standards.   **To protect public health and to provide safe transplantable tissue for our community, “expanded criteria” should never be used. There are no AATB, EBAA or FDA “Expanded Criteria” to determine donor suitability.** |
# Lifesharing Tissue Banking
## Best Practices

<table>
<thead>
<tr>
<th>Criteria and Best Practices for Reputable Tissue Banks and Eye Banks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality Assurance Program:</strong> The organization will demonstrate that they provide the highest quality and safe tissue by meeting multiple regulations and standards and operating a rigorous Quality Assurance Program managed by experienced and credentialed quality experts.</td>
</tr>
<tr>
<td><strong>Education:</strong> The organization should also provide donation education. Lifesharing and San Diego Eye Bank have a contract with all hospitals in San Diego and Imperial Counties to provide donation recovery services and professional education. They also provide ongoing donation awareness education to the local community.</td>
</tr>
<tr>
<td><strong>Tissue Recovery Suite:</strong> The organization should recover tissues in a dedicated aseptic Tissue Recovery Suite that ensures an environment that reduces tissue cross-contamination and potential disease transmission. Lifesharing specially trained technicians recover tissues in a dedicated aseptic Tissue Recovery Suite. Lifesharing does not recover tissues in an environment that is potentially hazardous to the recipient, such as funeral homes, mortuaries and morgues.</td>
</tr>
<tr>
<td><strong>Ocular Tissue Recovery:</strong> Eye tissue recovery must be done aseptically by specially trained technicians. The ocular tissue can be recovered at any facility as long as it is recovered aseptically.</td>
</tr>
<tr>
<td><strong>Ocular &amp; Tissue Recovery Standards:</strong> The organization follows national standards established by the AATB and EBAA to ensure the safe recovery of tissues to reduce contamination, cross-contamination and potential disease transmission to recipients of the donor tissue. Lifesharing is AATB Accredited and San Diego Eye Bank is EBAA Accredited and they rigorously follow the accreditation standards.</td>
</tr>
<tr>
<td><strong>Disposition of Tissue:</strong> The organization should provide, when needed, detailed reports regarding disposition of donors and tissues:</td>
</tr>
<tr>
<td>- Exact tissues recovered and if it is used for transplant or research</td>
</tr>
<tr>
<td>- Tissue Processors that the tissue is sent to</td>
</tr>
<tr>
<td>- Discarded tissue: where it is discarded</td>
</tr>
<tr>
<td>- Lifesharing provides outcome information</td>
</tr>
<tr>
<td>- All ocular tissues are tracked for usage and final distribution.</td>
</tr>
<tr>
<td><strong>Tissue and Eye for Research:</strong> San Diego Eye Bank and Lifesharing work with approved research professionals. They use a Trained Designated Requestor (Family Services Coordinator) and must gain authorization for research from a decedent’s family. The Eye and Tissue Bank should clarify:</td>
</tr>
<tr>
<td>- Uses of tissues or whole limbs used</td>
</tr>
<tr>
<td>- Which research entities and how are they approved (See Research Tab)</td>
</tr>
<tr>
<td>- Types of research i.e. cellular, organ, education, medical devices, medical surgical techniques &amp; training</td>
</tr>
<tr>
<td><strong>Transportation of Ocular &amp; Tissue:</strong> All tissues should be packaged aseptically, placed on ice, and shipped immediately in an validated shipping container. The Ocular/Tissue Bank should be able to provide packaging procedures and validation protocol for shipper. Lifesharing and San Diego Eye Bank, provide these services and upholds these industry standards.</td>
</tr>
<tr>
<td><strong>No Cost to Families for Donation:</strong> Families should never be assessed extra charges related to the donation process. Tissue &amp; Eye Banks should have policies in place to address any extra cost incurred by the Funeral Home due to donation.</td>
</tr>
<tr>
<td><strong>No Compensation for Donation:</strong> Federal regulations prohibit the family from receiving compensation for donation.</td>
</tr>
</tbody>
</table>
What is an Organ Procurement Organization (OPO)?

• Federally Designated to facilitate organ recovery for a specific geographic area.
  » Hospitals must notify OPO of every death and imminent death in a timely manner
  » Ensure identification, referral, and maintenance of potential donor

• Regulated by Centers for Medicare
  » Performance metrics: Number of donors and organs
Facts about Organ Donation

• Each day **78** people receive a second chance at life in the US, but **18** people die waiting.

• A single organ donor can save the lives of up to **8** people.

• You are **10** times more likely to need a transplant then be a donor.

• > **123,120** people are on the US organ waiting list.

• All major religions support or permit donation.

• Donation do not cost the funeral home or the family anything.
Organ Donation

A single organ donor can save the lives of up to eight people. Currently over 110,000 people in the U.S. are on the waiting list for an organ transplant. Nearly 1,600 people are on the waiting list for an organ transplant in San Diego and Imperial Counties.

**LUNGS**
Replace damaged or defective lungs due to conditions such as cystic fibrosis, pulmonary hypertension, emphysema and pulmonary embolism.

**LIVER**
Replace diseased or damaged livers due to conditions such as birth defects of the liver or bile ducts, chronic liver conditions or infections like hepatitis.

**PANCREAS**
Replace diseased or damaged pancreas due to diabetes. Often transplanted with a kidney because diabetes affects both organs.

**HEART**
Replace diseased or damaged heart due to conditions such as cardiomyopathy, heart failure, myocarditis and heart disease.

**KIDNEYS**
Replace diseased or damaged kidneys due to conditions such as high blood pressure, diabetes and polycystic kidney disease.

**INTESTINES**
Most intestinal transplants are performed on infants or children due to conditions such as twisted or blocked intestines or short-gut syndrome.
Organ Donation Process

• Organ Donation: 0 – 80 years of age
  » Up to 8 organs transplanted
    • Patient is declared dead
    • Lifesharing meets with family: Registry Consent or Family Consent
    • 24-48 hours of donor management in the ICU
      • Testing and medical review
    • Identify recipients
    • Coordinate surgical teams arrival
    • Organ recovery commences in O.R. while heart is beating and oxygen ventilating
    • Organs are transported and transplanted at the hospital of the intended recipients
Organ, Tissue and Whole Body Donation for Research and Education

• Per California State Law Section 7150.50, organ, tissue or whole body donation for research and education can only be made to the following organizations:
  » Hospital
  » Accredited Medical School
  » Dental School
  » College or University, or
  » Procurement Organization (OPO, Eye Bank, Tissue Bank*)
    *Tissue Bank must be registered with the FDA or licensed as a Tissue Bank by the State of California

➢ To protect your Funeral Home and the families you work with, please contact us to ensure the legality of research organizations.
Tissue for Research and Education

• Lifesharing partners with local research facilities and recover tissue for research and educational purposes
  » Brain
  » Spine
  » Stem cells, etc

• Research facilities go through a thorough screening process before being approved by Lifesharing
  » Researcher credentials
  » Research purposes
  » Final tissue disposition
  » Ethics and conflict of interest evaluation
Whole Body Donation for Research and Education

• Whole Body Donation for Research is available through **UCSD School of Medicine**

• The next of kin or executor can contact the Program by calling 24/7: **(858) 534-4536**

• More information is available at: https://meded.ucsd.edu/index.cfm/body_donation_program/
Reimbursement

Lifesharing, a division of UC San Diego Health System, realizes that procurement of organs and tissues from a deceased donor may result in extra efforts during the embalming process. The following guidelines are intended to provide reimbursement to funeral directors and embalmers for any extra preparation time required to properly embalm the remains of an organ and/or tissue donor, and to ensure that any additional costs are not incurred by the donor family. In an effort to avoid this burden, Lifesharing will reimburse San Diego and Imperial County funeral homes for the extended efforts and supplies required to prepare the descendent for funeral viewing.

To verify that embalming services have been performed by the funeral home on the donor body, the Lifesharing requests the funeral home provide the following information on the reimbursement invoice:

• Descendant’s name, date of birth, and a copy of the death certificate
• Confirmation of the embalming and the date the embalming took place.
• Reimbursement is accepted in lieu of additional charges to the decedent's family.
• Signature of person authorized to sign for the funeral home.

The reimbursement invoice with the above statement should be on the funeral home letterhead

**Reimbursable Amount: $250.00**

Mail invoice to: Lifesharing
**ATTN: Funeral Services**
3465 Camino Del Rio South #410
San Diego, CA 92108
Training Opportunities

Lifesharing presents programs on organ and tissue donation and post-procurement care of donors throughout the year.

From our annual seminar for funeral and forensic service professionals to periodic wet labs for mortuary science students and professional embalmers, we are committed to giving you the information and skills you need to help honor the decision to donate.

» Funeral Professional Educational Forums
» Embalming Workshops
» In-Service Training for Funeral Homes upon request
Caring for the Donor Family

As a care-giving professional, a funeral home can provide critical support to donor families by providing information to help by respecting the family’s donation decision and their confidentiality. Although donation could affect the appearance of the body to some degree (depending on the nature and extent of the donation), families should be assured that the body has been reconstructed as completely as possible, and that donation itself should not interfere with plans for open casket services. Questions about scheduling of visitation and services will also be discussed and need to take the donation process into account.

Donor families repeatedly stated that they want, need and can handle full information about the donation both before and after they give consent. Answering their questions directly and completely should be an integral part of the services provided by their health care professionals, procurement agencies and funeral directors. Lifesharing does provide support services for donor families and does help families contact community-based services, grief counseling, support groups, education programs, etc. Funeral directors can assist families by encouraging them to utilize the resources available through Lifesharing.

Additional services that Lifesharing offers donor families are:

» Lifesharing Donor Remembrance Plaques - placed in all funeral homes to honor those that have become donors

Lifesharing Donor Remembrance Plaque
Funeral Advisory Board

As part of our commitment to working in partnership with Funeral Homes in San Diego County, a funeral advisory board meets annually to identify and implement policies, outreach and educational events that improve Lifesharing's commitments to assisting families with their journey through death and grief and to improve organ and tissue donation.

Comprised of practicing morticians, the Lifesharing Funeral Advisory Board advocates that funeral professionals adopt an ethical code of conduct designed to facilitate and promote cooperation with ongoing organ, tissue and cornea procurement programs.

Funeral Advisory Board Members:

- Debbie Allen
  Eternal Hills Mortuary

- Deanne Osuna
  El Cajon Mortuary

- Grant Conrad
  Conrad Lemon Grove Mortuary

- Alejandro Escalera
  Humphrey Mortuary

- Desmond Fields
  Greenwood Mortuary

- Brian Gisotti
  Central Care Cremation and Burial

- Dallas Johnson
  El Cajon Mortuary

- Richard Jungus
  California Funeral Alternative

- Desmond Fields
  Greenwood Mortuary

- Vic Savino
  Legacy Funeral Home

- Sheila Williams
  Williams San Diego Memorial Chapel
Contact Us

If you have any questions, please call our office at (619) 521-1983 and ask for a Tissue Manager.

To refer a donor, call our 24/7 referral line at 1-800-4-A-DONOR (1-800-423-6667)

Main Office
3465 Camino Del Rio South, Suite 410,
San Diego, CA 92108
Fax: (619) 521-2833