

7.7 Amendments. Unless otherwise specifically provided herein, this Agreement may be amended or changed only by mutually written consent of LifeGift and the Hospital.

7.8 Governing Law and Venue. This Agreement shall be construed and enforced in accordance with the laws of the State of Texas, and venue shall lie in Harris County, Texas.

7.9 Captions. The captions contained herein are for reference purposes only and shall not affect the meaning of this Agreement.

7.10 Sovereign Immunity. Nothing herein shall be construed as creating any personal liability on the part of any officer or agent of any public body that may be a party hereto. Hospital neither waives nor forfeits any immunity from suit or liability it may have by operation of law.

7.11 Entire Agreement. This Agreement, together with exhibits and all other documents incorporated herein by reference, contains the entire understanding between the parties and supersedes all prior agreements, either oral or in writing, with respect to the subject matter hereof.

IN WITNESS WHEREOF, each of the parties hereto has executed this Agreement as of the date stated below.

LifeGift Organ Donation Center

By: _____
Name: _____
Title: _____
Date: _____
Address: _____

By: _____
Name: Samuel Miles Holtzman, III
Title: President and CEO
Date: _____
Address: 2510 Westridge Street
Houston, Texas 77054

ADDENDUM 1

CREREDENTIALING; QUALIFIED PERSONNEL^{3,4} Entry of LifeGift orders into patient chart following pronouncement of death.

Deceased patients whose families have consented to organ donation will be admitted to the care of "Dr. LifeGift" for the purposes of organ recovery. Use of Dr. LifeGift as the admitting physician identifies the patient as a deceased individual who is an organ donor. When writing orders in the donor's chart, LifeGift staff will use the moniker "Dr. LifeGift" and will follow with recording their name, credentials and position.

Example:

Add 20 meq to one liter D5.45 NS – administer at 125 cc/hr.

*Dr. LifeGift
John Roberts, CPTC, DCS*

³ Centers for Medicare and Medicaid Services, re: Qualifications and Credentialing.

CMS specifies that the OPO shall only send qualified individuals to perform donor organ recovery from deceased individuals and shall ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services. The OPO must also have credentialing records for physicians and other practitioners who routinely recover organs in hospitals. (Subpart G. Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations, Section 486.326 (a) – (d), Centers for Medicare and Medicaid Services.)

⁴ Joint Commission on Accreditation of Healthcare Organizations

On October 5, 1998 The Joint Commission issued the following clarification in the form of a Q & A:
Clarification of Credentialing and Privileging of Organ Recovery Teams

Q: Is a healthcare organization required to perform credentials review and grant clinical privileges to members of Transport Teams and Organ Recovery Teams for clinical intervention provided in the health care organization?

A: No. Transport Teams, such as for Neonatal ICU patients, trauma victims, long term care facility residents or burn patients, and Organ Recovery Teams, often contain licensed independent practitioners who would otherwise require clinical privileges to work within the facility. These teams often consist of individuals on rotational assignments, who may only infrequently visit the healthcare organizations. Their work is too limited to undergo performance improvement activity review at each site that is meaningful for the renewal of clinical privileges.

The Teams work as part of the healthcare organizations plan for continuity of care. The patient, although still in the healthcare organization, is transferred to the responsibility of the Team. When that occurs, the responsibility for the performance of the members of the Team as it applies to the patients and as required by Joint Commission standards, passes to the Team. Teams work in health care organizations on the basis of some form of agreement, whether a contract. Memorandum of understanding or regional governmental authority. It is the health care organization's responsibility to ensure that the agreement provides for qualified individuals who are properly authorized by their organizations.

Note: While this answer provides an exception to the usual procedures required for credentials review, privileging, competency and job descriptions, it does not remove the health care organization from its obligation to ensure that it enters into agreements that comply with JCAHO standards.

**LIFEGIFT ORGAN DONATION CENTER
DONOR INSTITUTION AGREEMENT**

EXHIBIT A

**FLAT FEE FOR USE OF OR FACILITIES FOR THE RECOVERY OF BONE AND
TISSUE**

Hospital and LifeGift agree to establish the following flat fees to be paid to Hospital by LifeGift for the use of Hospital's operating room facilities for the sterile recovery of bone and other tissues at Hospital:

\$550 for each "bone-only" donor; and

\$825 for each "bone and other tissue" donor.

Other tissues include heart valves, saphenous veins and skin.

**LIFEGIFT ORGAN DONATION CENTER
DONOR INSTITUTION AGREEMENT**

EXHIBIT B

ORGAN DONOR CASE RATES FOR HOSPITALS

Payment Structure: Effective October 1, 2007

Payment Profile*	Base Payment	Donor Profiles with serology***	For each additional echocardiogram, 2 D M-mode	For Operating Room Time > 6.5 Hours	For ICU > 24 hours
Donor Profile 1: With Cardiac Evaluation **	\$9,760	\$10,000	\$500	100% of charges	\$1000 for each additional 24 hour period
Donor Profile 1: Without Cardiac Evaluation	\$9,260	\$9,500		100% of charges	\$1000 for each additional 24 hour period
Donor Profile 2: With Cardiac Evaluation**	\$11,215	\$11,400	\$500	100% of charges	\$1000 for each additional 24 hour period
Donor Profile 2: Without Cardiac Evaluation	\$10,715	\$10,900		100% of charges	\$1000 for each additional 24 hour period
Donor Profile 3: With Cardiac Evaluation**	\$13,450	\$13,550	\$500	100% of charges	\$1000 for each additional 24 hour period
Donor Profile 3: Without Cardiac Evaluation	\$12,950	\$13,050		100% of charges	\$1000 for each additional 24 hour period
Medically unsuitable Donors	Lesser of 65% of Donor Profile 1 or Billed Charges	Base Payment Plus \$600	\$500	N/A	Included in base payment

* Profile 1: OR time less than 3 hours; Profile 2: OR time 3 to 4.5 hours; Profile 3: OR time 4.5 to 6.5 hours

** Cardiac evaluation includes 1 Echocardiogram, 2D M-mode

*** Serology = \$600

Revised 3/12/98; Revised 10/1/98; Revised 10/1/2000; Revised 10/1/2002; Revised 10/1/2004; Revised 10/1/2007

**LIFEGIFT ORGAN DONATION CENTER
TRANSPLANT CENTER ADDENDUM
To
DONOR INSTITUTION AGREEMENT**

This TRANSPLANT CENTER ADDENDUM ("Addendum Agreement") is made by and between LifeGift Organ Donation Center ("LifeGift"), a Texas nonprofit corporation, and _____ ("Hospital") effective as of _____.

WHEREAS, the parties desire to set forth the responsibilities of each with respect to the transplantation of donated organs and tissues.

WHEREAS, Hospital is a transplant center certified by the Centers for Medicare and Medicaid Services ("CMS") and approved by the United Network for Organ Sharing ("UNOS"), the Organ Procurement and Transplantation Network designated by CMS, to furnish directly, for specific organs, transplant and other medical and surgical specialty services required for the care of transplant patients,

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, LifeGift and Hospital agree as follows:

ARTICLE I

Responsibilities of LifeGift

In accordance with the National Organ Transplant Act, the rules and requirements of the Organ Procurement and Transplantation Network established under section 372 of the Public Health Services Act, and regulations published by the Secretary of Health and Human Services, and LifeGift policies, LifeGift shall have the following responsibilities:

1.1. Distribution System. LifeGift shall establish and maintain a system for the appropriate distribution of donated organs consistent with LifeGift policies, federal laws and regulations, and UNOS policies and rules. Such system shall provide that the organs recovered in the service area designated to LifeGift by CMS shall be placed for transplant in the same service area to the extent medically reasonable and permitted by UNOS rules and federal regulations.

1.2. Information on Donor Organs. LifeGift shall access the list of potential transplant recipients on local and national networks according to medical priority, matching criteria, compatibility standards, and such other criteria as CMS, UNOS, or LifeGift policies may require, and shall refer potential donor organs to Hospital on a 24-hour basis according to protocols developed by LifeGift that are consistent with UNOS rules and federal regulations.

1.3. Provisions of Donor Organs. In connection with providing organs and tissues to the Hospital for transplantation, LifeGift shall:

- 1.3.1. Arrange for appropriate tissue typing of donated organs;
- 1.3.2. Screen potential donor organs by obtaining available medical and social history and infectious disease test results;
- 1.3.3. Provide appropriate transportation arrangements for donor organs;

- 1.3.4. Provide organ procurement team members for recovery of donor organs;
- 1.3.5. Recover donor organs as appropriate and supply such organs to Hospital according to priorities established by UNOS, CMS, and LifeGift policies, provided that LifeGift policies shall not be inconsistent with the medical priority and other requirements of UNOS and CMS;
- 1.3.6. Provide written donor information to Hospital on each donor organ procured;
- 1.3.7. Maintain for seven years written records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related information required by CMS;
- 1.3.8. Maintain a recipient waiting list;
- 1.3.9. Perform such other services as may be required of a Medicare certified OPO.

1.4. Compliance With Appropriate Laws and Standards. LifeGift shall comply with federal and state laws and regulations with respect to the procurement of organs as an OPO designated by the Secretary of Health and Human Services. Additionally, LifeGift shall comply with Hospital policies and procedures that relate directly to the procurement of organs or organs donations and that are consistent with federal and state statutes and regulations and UNOS rules.

ARTICLE II

Responsibilities of Transplant Center

In accordance with the requirements of the U.S. Department of Health and Human Services and Hospital's membership in the Organ Procurement and Transplantation Network, Hospital shall have the following responsibilities:

2.1 Information Regarding Potential Recipients. Hospitals shall provide information on potential organ transplant recipients to LifeGift. Hospital shall continuously update the list of waiting potential recipients as their medical priorities or compatibility factors change. In addition, Hospital shall provide LifeGift with recipient selection criteria for all organs for which it has a transplant program.

2.2 Transplantation Facilities and Staffing. In order to ensure that the organs provided by LifeGift are distributed in a manner that ensures the greatest likelihood of successful transplantation, Hospital agrees that it shall:

- 2.2.1 Provide 24-hour on-site coverage for transplantation of organs with qualified transplant surgeons, physicians, and ancillary transplantation staff;
- 2.2.2 To the best of its ability, maintain a full time transplant coordinator on-site to ensure coordination of transplantation for all patients transplanted at that center and to ensure a timely response to the offer of an organ;

- 2.2.3 To the best of its ability, maintain a transplantation medical director to ensure a timely response to the offer of an organ and the timely transplantation of that organ;
- 2.2.4 Maintain availability of operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;
- 2.2.5 Exhibit evidence of collaborative involvement at the Hospital, at a minimum, with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hematology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;
- 2.2.6 Maintain immediate access to microbiology, clinical chemistry, tissue typing, radiology and blood banking services, as well as the capacity to monitor immunosuppressive drugs;
- 2.2.7 Make available psychiatric and social support services for transplant recipients and their families at the Hospital;
- 2.2.8 Acknowledge that the transplant surgeon shall provide to the potential recipient or his or her representative relevant information provided by LifeGift regarding the medical and social history of the donor and be responsible for the informed consent of the organ recipient;
- 2.2.9 If the organ is not transplanted into the recipient for which the organ was designated by LifeGift in accordance with UNOS criteria, the Hospital agrees to notify LifeGift immediately so that LifeGift may attempt to reallocate the organ for an alternate recipient in accordance with UNOS rules and CMS regulations; if Hospital accepts the organ but is unable to use the organ, Hospital remains responsible for payment of all standard acquisition charges unless the organ is accepted by another hospital and transferred to the other hospital;
- 2.2.10 Maintain for seven years written records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related records required by CMS; and
- 2.2.11 Provide a physician call schedule listing the physician to be called for each type of organ offer prior to the month in which call will be taken.

2.3 Follow-Up Information. Hospital shall provide LifeGift with recipient follow-up data on all transplants and other organ-transplant-data as requested by LifeGift.

2.4 Compliance With Appropriate Laws and Standards. Hospital agrees to comply with federal and state laws and regulations and UNOS rules with respect to the transplantation of organs. Additionally, Hospital agrees to comply with LifeGift's policies and procedures attached hereto and incorporated herein, as they may be amended from time to time that relate to the provision of donated organs or tissues. Amendments shall be provided to Hospital in a timely manner.

ARTICLE III

Reimbursement

3.3 Standard Acquisition Fees for Organs - Reimbursement. As payment for the services provided and the costs incurred by LifeGift in recovery and provision of organs and/or tissues, Hospital agrees to reimburse LifeGift for services that LifeGift performs with respect to organ procurement, storage, transportation, and other costs related to the procurement of organs on behalf of Hospital in accordance with the invoices supplied by LifeGift. A schedule of current standard acquisition costs is attached and incorporated herein by this reference. These costs may change from time to time and are subject to Medicare and Medicaid regulations and other applicable laws.

3.4 Payment of Standard Acquisition Fees for Organ Reimbursement. LifeGift shall provide an invoice to Hospital for each organ supplied to Hospital, which invoice will reflect the standard acquisition cost for supplying the services necessary for the procurement, storage, and transportation of organs supplied to Hospital. Hospital shall make payment to LifeGift in accordance with the invoice within 30 days from its receipt of the invoice from LifeGift.

IN WITNESS WHEREOF, each of the parties hereto has executed this Addendum Agreement as of the date stated below.

LifeGift Organ Donation Center

By: _____
Name: _____
Title: _____
Date: _____
Address: _____

By: _____
Name: Samuel Miles Holtzman, III
Title: President and CEO
Date: _____
Address: 2510 Westridge Street
Houston, Texas 77054

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の 編集者名	書 籍 名	出版社名	出版地	出版年	ページ
なし							

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
福嶋教偉	脳死臓器提供摘出手技 心臓・肺	今日の移植	Vol.21 No.5	419-423	2008年
重村 朋子 横田裕行	臨床的脳死患者家族の 心理過程に関する一考 察	脳死・脳蘇生	20	63-67	2008年