

3. 臨床的脳死診断からお見送りまでの対応についてお尋ねします。

1) その間、倫理委員会（脳死判定委員会等）を開催しましたか。（ ）の中に○をつけてください。

（ ）開催しない

（ ）開催した（            回）

2) 貴施設において、倫理委員会（脳死判定委員会等）は必要でしたか。（ ）の中に○をつけ、それぞれ理由をご記載ください。

（ ）必要なかった

（ ）必要であった

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3) 法的脳死判定の実施において、対処に困難だったことがありましたか。（ ）に○をつけ、ある場合はその内容と対処方法をご記載ください。

（ ）なかった

（ ）あった

<b>【内容】</b>
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<b>【対処方法】</b>
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- 4) 提供者の家族との関係についてお尋ねします。家族から意見、苦情（どんなことでも構いません）など、思いを表出されたことはありましたか。下記より選んで（ ）に○をつけ、ある場合は、その時期、内容、対応についてご記載ください。

（ ） なかった

（ ） あった

【時期】 （ ） に○をつけてください

（ ） 臨床的脳死診断から承諾書作成まで

（ ） 法的脳死判定中

（ ） 死亡確認後から摘出手術開始まで

（ ） 摘出手術中

（ ） 摘出手術終了からお見送りまで

（ ） 退院後

（ ） その他（ ）

【内容】

  <hr/>  
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【対応】 ※対応したことがあった場合

  <hr/>  
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4. 脳死下臓器提供終了後についてお尋ねいたします。

- 1) 移植コーディネーターからの定期的な報告（提供者の家族の様子や移植者の経過報告）は必要ですか。（ ）の中に○をつけてください。

（ ） 必要ない

（ ） 必要である

- 2) 脳死下臓器提供後、今後に向けて院内で対応したことはありますか。

（ ） に○をつけ、ある場合は、該当する内容に○をつけてください。

（ ） ない

（ ） ある

反省会 ・ マニュアルの作成、改訂 ・ 報告会 ・ 院内誌（学内誌等を含む）への掲載 ・ シミュレーションの開催 その他（ ）
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5. 「脳死臓器移植に関する検証資料フォーマット」(以下、検証フォーマット)についてお尋ねします。(注意) (検証資料を既に記載、提出した施設のみご回答ください)
- 1) 検証フォーマットの記載を終えて、次の事例に活かそうと感じたことはありましたか。具体的にご記載ください。


- 2) 第三者検証会議の医学的作業班との面談で、指摘された点がありましたか。


**脳死下臓器提供時の摘出チーム(移植医)の対応について**

1. 摘出チームの対応(第三次評価、摘出手術)は適切でしたか。
- 大変適切だった ←————→ 全く適切でなかった  
( 3 ・ 2 ・ 1 ・ 0 )
2. 摘出チーム(移植医)への要望がございましたら、ご記載ください。


## 脳死下臓器提供時の移植コーディネーターの対応について

1. 主治医から見て、移植コーディネーターの対応が適切であったか、最も当てはまる数字に○をつけてください。

	大変適切だった	←	→	全く適切でなかった			
①主治医との関わり	( 3	・	2	・	1	・	0 )
②看護師との関わり	( 3	・	2	・	1	・	0 )
③家族との関わり	( 3	・	2	・	1	・	0 )
④院内調整	( 3	・	2	・	1	・	0 )
⑤提供後の対応（報告等）	( 3	・	2	・	1	・	0 )

2. 移植コーディネーターへの要望がございましたら、ご記載ください。


- 脳死下臓器提供の一連の過程において、改善してほしい点、ご意見がございましたら、ご自由にご記載ください。


記載者

施設名：.....

ご所属：.....

ご芳名：.....

ご協力ありがとうございました。

平成20年12月29日

平成20年度厚生労働科学研究費補助金  
移植医療におけるコーディネートに関する研究

主任研究者 小中 節子

(日本臓器移植ネットワーク)

分担研究者 横田 裕行

(日本医科大学大学院

侵襲生体管理学)

「提供側からみたドナー管理のあり方に関する研究」に関するアンケートのご協力をお願い

拝啓 時下ますますご清祥のこととお慶び申し上げます。

わが国では平成9年に臓器の移植に関する法律が施行されてから現在までに76例の脳死下臓器提供が行なわれ、320名への臓器移植が行われました。

臓器提供は、臓器提供病院、臓器移植病院などの関連施設とあっせん機関である日本臓器移植ネットワークとが連携しながら手続きを進めております。平成15年より臓器提供数は増加傾向を示し、現在国会提出中の法律改定により更に増加が想定され、より適切で円滑な臓器提供時のコーディネートの構築が急務とされ、平成20年度厚生労働科学研究費補助金事業「移植医療におけるコーディネートに関する研究」を実施することとなりました。

そこで今回、「提供側からみたドナー管理のあり方に関する研究」を課題とし、脳死下臓器提供をご経験された施設を対象にアンケート調査を実施することになりましたので、ご協力いただきたく宜しくお願い申し上げます。アンケートは主治医を対象としておりますが、異動等により当時の主治医がいない場合は、可能な限りご協力いただければ幸いに存じます。

つきましては、大変お忙しいところ恐縮に存じますが、平成21年1月23日(金)までに同封の封筒にてご返信いただきますよう重ねてお願い申し上げます。

本調査結果を元に臓器提供病院側のマニュアルを作成するとともに円滑な臓器提供の実施と臓器提供・移植医療の普及啓発に役立てていきたいと存じます。

なお、個人情報保護法に則り、情報の取り扱いに関しましては細心の注意を払い、個別の病院名や個人名は一切公表いたしません。また、研究結果につきましては、皆様にご報告させていただきます。何卒ご理解とご協力のほど宜しくお願い申し上げます。

ご不明な点は、横田までご連絡いただきますようお願い申し上げます。

末筆になりましたが、貴殿の益々のご活躍を心よりお祈り申し上げます。

敬具

[連絡先]

〒113-8603 東京都文京区千駄木1-1-5

日本医科大学大学院侵襲生体管理学(救急医学)

主任教授 横田 裕行

TEL:03-3822-2131 内線 6969 FAX:03-3821-5102



平成21年1月6日

脳死下臓器提供施設  
病院長 様

平成20年度厚生労働科学研究費補助金  
移植医療におけるコーディネートに関する研究  
主任研究者 小中 節子  
(日本臓器移植ネットワーク)  
分担研究者 横田 裕行  
(日本医科大学大学院  
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敬具

[連絡先]

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日本医科大学大学院侵襲生体管理学(救急医学)  
主任教授 横田 裕行  
TEL:03-3822-2131 内線 6969 FAX:03-3821-5102

平成 21 年 1 月 6 日

社団法人日本臓器移植ネットワーク  
医療本部長 小中 節子

平成 20 年度厚生労働科学研究「移植医療におけるコーディネートに関する研究」  
からのアンケート協力依頼

拝啓 時下ますますご清祥のこととお慶び申し上げます。

平素より当社団の活動に対し、ご支援、ご協力を賜り厚くお礼申し上げます。

さて、この度、下記のとおり、アンケートへの協力依頼がございましたので、ご連絡申し上げます。このアンケートは脳死下臓器提供を経験された施設を対象とした調査ですが、脳死下臓器提供時に施設名を公表していない施設に関してのみ、当社団から送付をさせていただいております。

詳細につきましては、同封いたします書類をご確認ください。

末筆になりましたが、貴殿の益々のご活躍を心よりお祈り申し上げます。

敬具

#### 記

#### ○ 協力依頼内容

「提供側からみたドナー管理のあり方に関する研究」に関するアンケート  
主任研究者

社団法人日本臓器移植ネットワーク 医療本部 小中節子

分担研究者

日本医科大学大学院侵襲生体管理学（救急医学） 横田 裕行

以上

<b>Hiroyuki Yokota, MD / Juntaro Ashikari, MS</b>			
<b>November-08</b>			
	<b>Meet With:</b>	<b>Topic</b>	<b>Location</b>
<b>Friday, November 21</b>			
7:00	Trauma Surgeons	Trauma Service Line	Memorial Hermann Hospital
9:00	Sam Holtzman, CEO	LifeGift Overview	LifeGift Office - 2nd Floor, Sam's Office
10:00	Janice Whaley, Managing Director - Clinical Operations Southeast Region	SE Organ/ Tissue Operations	2nd Floor, Janice's Office
11:00	Lunch with Pat Wood, MD LifeGift Medical Director	Medical Directors Role	2nd Floor Conf Room
1:00	Carla Arreola, Communication Center Manager	Communications Center	Communications Center
2:00	Tina LeVert, Manager, Level One Trauma Programs	Consent	2nd Floor, Tina's Office
3:00	Brad Scot, MD, Director of Minimally Invasive Surgery/Director of Surgical Emergency Center, Ben Taub General Hospital	Hospital Collaboration in the Donation Process	4th Floor, Ben Taub
4:00	Teresa Shafer, COO	Operations	via Conference call
6:00	Sam Holtzman, CEO (Laura), Charles Van Buren, MD, Janice Whaley, Tina LeVert	Dinner	Vick & Anthony's Steakhouse
7:00		On call for Donors or Referrals	Area Hospitals
<b>Saturday, November 22</b>			
7:00	Tina Levert / Elena Mendoza	Rounds	Memorial Hermann Hospital and Ben Taub General Hospital
9:00		On call for Donors or Referrals	Area Hospitals
10:00			
11:00			
12:00			
1:00			
2:00			
3:00			
4:00			



BenTaub General Hospital ICU In-Services

**BTGH CY 08**

**CCU (Donna\_Quinn@hchd.tmc.edu) 713-873-2591**

**Quarterly 2nd Friday**

Month	Day	Year	Time
January	11th	2008	12pm-1pm
April	11th	2008	12pm-1pm
August	8th	2008	12pm-1pm
December	12th	2008	12pm-1pm

**CCU (Donna\_Quinn@hchd.tmc.edu) 713-873-2591**

**Quarterly 3rd Tuesday**

Month	Day	Year	Time
April	15th	2008	20:00-21:00
August	19th	2008	20:00-21:00
December	15th	2008	20:00-21:00

**General Surgery (mcleee@bcm.edu) 713-873-3949**

**Quarterly 3rd Tuesday**

Month	Day	Year	Time
March	25th	2008	11:30pm-12:30pm
July	15th	2008	11:30pm-12:30pm
November	18th	2008	11:30pm-12:30pm

**MICU (Andrea\_James@hchd.tmc.edu) 713-873-2374**

**Quarterly 4th Tuesday**

Month	Day	Year	Time
March	25th	2008	12pm-1pm 20:30-21:30
July	25th	2008	12pm-1pm 20:30-21:30
November	25th	2008	12pm-1pm 20:30-21:30

**PICU (deborah\_bates@hchd.tmc.edu) 713-873-3044**

**Quarterly 3rd Thursday**

Month	Day	Year	Time
March	20th	2008	12pm-1pm
July	17th	2008	12pm-1pm
November	20th	2008	12pm-1pm

**Pedi ICU Residents**

**Monthly 1st Friday**

Month	Day	Year	Time
January	4th	2008	12pm-1pm
February	1st	2008	12pm-1pm
March	7th	2008	12pm-1pm
April	4th	2008	12pm-1pm
May	2nd	2008	12pm-1pm
June	6th	2008	12pm-1pm
July	4th	2008	12pm-1pm
August	1st	2008	12pm-1pm
September	5th	2008	12pm-1pm
October	3rd	2008	12pm-1pm
November	7th	2008	12pm-1pm
December	5th	2008	12pm-1pm

**NICU (Leela\_Joseph@hchd.tmc.edu) 713-873-2787**

**Quarterly 2nd Friday**

Month	Day	Year	Time
March	14th	2008	11pm-12pm
July	11th	2008	11pm-12pm

BenTaub General Hospital ICU In-Services

November 14 2008 11pm-12pm

TSICU (Rizza\_Isagan@hchd.tmc.edu) 713-873-2741

Every other month 1st Monday

Month	Day	Year	Time
February	4th	2008	1pm-2pm
April	7th	2008	1pm-2pm
June	2nd	2008	1pm-2pm
August	4th	2008	1pm-2pm
October	6th	2008	1pm-2pm
December	1st	2008	1pm-2pm

BenTaub General Hospital Tissue In-Services

**BTGH CY 08**

**4A (grace\_okoro@hchd.tmc) 713-873-  
Quarterly 3rd Thursday**

Month	Day	Year	Time
February	21st	2008	9:00-9:30
			20:00-20:15
June	19th	2008	9:00-9:30
			20:00-20:15
October	16th	2008	9:00-9:30
			20:00-20:15

**4B (tammy\_dale@hchd.tmc) 713-873-  
Quarterly 3rd Thursday**

Month	Day	Year	Time
February	21st	2008	9:30-10:00
			20:30-20:45
June	19th	2008	9:30-10:00
			20:30-20:45
October	16th	2008	9:30-10:00
			20:30-20:45

**4D (leela\_joseph@hchd.tmc) 713-873-2787  
Quarterly 3rd Thursday**

Month	Day	Year	Time
February	21st	2008	10:00-10:30
			21:00-21:15
June	19th	2008	10:00-10:30
			21:00-21:15
October	16th	2008	10:00-10:30
			21:00-21:15

**LIFEGIFT ORGAN DONATION CENTER  
DONOR INSTITUTION AGREEMENT**

This DONOR INSTITUTION AGREEMENT ("Agreement") is made by and between LifeGift Organ Donation Center ("LifeGift"), a Texas nonprofit corporation, and ("Hospital") effective as of \_\_\_\_\_.

WHEREAS, LifeGift is an organ procurement organization ("OPO") established to perform and coordinate the recovery, preservation and transportation of organs and tissues;

WHEREAS, LifeGift has been designated by the Secretary of Health and Human Services as a Medicare-certified OPO to procure organs and tissues from organ or tissue donors who die in hospitals and to provide organs and tissue to hospitals that perform organ transplants;

WHEREAS, OPOs, hospitals, and health care facilities are required by federal and state laws and regulations to develop protocols to identify potential organ and tissue donors and to establish a reliable system of acquiring, preserving, and transporting donated organs and tissue within their service areas;

WHEREAS, the Centers for Medicare and Medicaid Services ("CMS") has issued regulations that require collaboration between OPOs and hospitals to maximize organ and tissue donation in the hospital. 42 CFR § 482.45;

WHEREAS, these regulations increase the importance of the OPO in a hospital's organ procurement program and broaden the OPO's role in (i) defining the criteria used by hospitals to identify potential organ and tissue donors; (ii) determining the medical suitability of potential donors; (iii) educating the hospital's staff regarding organ donation issues; (iv) reviewing hospital death records to improve identification of potential donors; and (v) collaborating with the hospital to define protocols with regard to the hospital's required notification of the OPO of all patients whose death is imminent or who have died in the hospital;

WHEREAS, the parties desire to create a collaborative model for the donation process within the hospital based on industry recognized organ and tissue donation best practices;

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

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

**ARTICLE I**

**Definitions**

For purposes of this Agreement, the following terms shall have the meanings ascribed to them in this Article I.

DNR-ABR.DOC Revised 1/22/98  
Revised 10/1/2000  
Revised 12/2002  
Revised 04/2004  
Revised 12/2007



**1.1 Organ.** The term "organ" means a human kidney, heart, lung, pancreas, liver or other human organ that may be used for human transplantation.

**1.2 Tissue.** The term "tissue" refers to bone, skin, corneas, eyes, heart valves, saphenous veins, or any other human tissue that may be used for human transplantation.

**1.3 Potential Donors.** The term "potential donors" means persons who meet the criteria established in 1.4 or who die in circumstances (including ages and causes and conditions of death) that would make at least one of their solid organs or tissue acceptable to transplant.

**1.4 Imminent Death.** A patient with severe, acute brain injury, disease or illness that may or may not be traumatic in origin; and:

- (1) Who requires mechanical ventilation; and,
- (2) Is in an Intensive Care Unit or Emergency Department; and,
- (3) Has clinical findings consistent with a Glasgow Coma Score (GCS) that is less than or equal to a mutually-agreed-upon threshold (such as 4 or 5); or
  - (a) For whom physicians are evaluating a diagnosis of brain death; or
  - (b) For whom a physician has ordered that life-sustaining therapies be withdrawn, pursuant to the family's decision.

**1.5 Timely Notification.** Timely notification means notification to LifeGift of an imminent death (as defined in section 1.4 herein) to LifeGift within one hour of the patient's meeting the criteria for imminent death. Notification shall be made *prior* to the withdrawal of any life sustaining therapies. With respect to cardiac death, timely notification means notification to LifeGift within one hour of the cardiac death.

**1.6 Clinical Trigger.** A clinical trigger means imminent death as defined in section 1.4 above, or cardiac death, which shall be reported to LifeGift in a timely manner as described in section 1.5.

## ARTICLE II

### Responsibilities of LifeGift

In accordance with the National Organ Transplant Act and regulations published by the Secretary of Health and Human Services, LifeGift shall have the following responsibilities:

**2.1 Referral Source.** LifeGift agrees to be the sole referral source of the Hospital for all organ and tissue placement. LifeGift shall provide to the Hospital a one phone call referral system whereby the Hospital will be able to call the LifeGift referral line [1-800-633-6562] when a hospital death occurs. To the extent LifeGift cannot provide the organ and/or tissue placement, LifeGift shall refer the organ and/or tissue to other organ, tissue and/or eye banks.

**2.2 Development of Donor Identification Protocols.** LifeGift agrees to assist Hospital in the development of protocols with regard to the referral of hospital deaths as potential organ and tissue donors and the clinical maintenance of potential organ and/or tissue donors. LifeGift shall determine and apply initial selection criteria to identify potential organ and/or tissue donors. The transplant surgeon (and the patient) ultimately determines whether an organ is suitable for a particular patient.



**2.3 Training of Hospital Personnel.** LifeGift agrees to assist in the training of Hospital personnel who are involved in the referral process. LifeGift shall conduct periodic in-service education programs for administrative and professional personnel at Hospital regarding the referral and maintenance of potential organ and/or tissue donors.

**2.4 Determination of Medical Suitability.** LifeGift shall make the initial assessment regarding the patient's medical suitability or unsuitability for organ recovery. (42 CFR §482.45 (a) (1). LifeGift will obtain information from Hospital medical and nursing staff regarding the patient's medical condition and LifeGift will decide whether the organs will be offered to transplant centers. The final decision to accept a particular organ will remain within the discretion of the potential recipient, the transplant surgeon and/or physician responsible for the care of the potential recipient.

**2.5 Donor Consent and Documentation.** LifeGift shall notify and provide assistance to persons authorized to make a donation on behalf of a potential donor pursuant to Section 692.004 of the Texas Anatomical Gift Act regarding the options for organ and/or tissue donation. LifeGift shall in cooperation and conjunction with Hospital, complete and maintain documentation for requests and/or consents relating to organ and/or tissue donations.

**2.5.1** LifeGift shall be responsible for making the request for donation from family members and/or person(s) authorized to make a donation on behalf of a potential donor unless designated requestor training has been provided to specified medical and/or nursing staff by LifeGift as described in 42 CFR §482.45 (a)(3) and in the Texas Anatomical Gift Act, Chapter 692A of the Texas Health & Safety Code. If designated requestor training has been provided, then LifeGift shall provide assistance to specified medical and/or nursing staff in making the donation request.

**2.6 Release for Donation from Medical Examiner.** In circumstances when permission of the local medical examiner is required for organ and/or tissue donation, LifeGift shall obtain such permission pursuant to applicable laws.

**2.7 Designation of Recovery Teams and Distribution of Organs.** LifeGift shall assume responsibility for the designation of recovery teams, preservation, transportation, and distribution of organs and tissues that are recovered from Hospital for transplantation purposes. LifeGift shall coordinate activities between Hospital and other organ and tissue procurement agencies in the event of a multiple organ and/or tissue donation.

**2.8 Quality Assurance.** LifeGift agrees to assist Hospital in compliance with Joint Commission on Accreditation of Health Care Organizations ("JCAHO") standards and Section 692.013 of the Texas Anatomical Gift Act as well as other applicable state and federal laws and regulations. In furtherance thereof, LifeGift agrees to the following:

**2.8.1 Hospital Review System.** LifeGift shall assist the Hospital in the development of a Hospital review system, if required, for the periodic review of the donation procurement process.

**2.8.2 Periodic Reviews.** LifeGift shall conduct periodic reviews of Hospital death records and random patient charts to assist Hospital in defining the size of the potential organ and tissue donor pool, determining compliance with both Medicare and JCAHO quality assurance standards, and identifying opportunities to improve organ and tissue donation.

**2.8.3 Written Reports.** LifeGift shall provide Hospital with periodic written reports pertaining to organ and tissue donor referral and donation activity.

**2.9 Routine Notification of Hospital Deaths.** LifeGift agrees to cooperate fully with Hospital on a program of routine notification of all Hospital deaths. In connection with such program LifeGift shall be responsible for the following:

**2.9.1 Communications Center.** LifeGift shall maintain an in-house communications center at LifeGift to support Hospital's routine notification of imminent deaths and or deaths.

**2.9.2 Evaluation of Hospital Deaths.** LifeGift shall evaluate all Hospital deaths to determine medical suitability or unsuitability for donation.

**2.9.3 Donor Notification.** LifeGift's health care professionals, who are trained to recognize and manage the special needs of potential donor families, shall offer the option of donation to the legal next-of-kin of all medically suitable donors.

**2.9.4 Statistical Summaries.** LifeGift shall provide Hospital with regular statistical summaries of Hospital-specific notification call activity to support verification of Hospital compliance with legislative, accreditation and regulatory requirements pertaining to donation.

**2.10 Authorization to Conduct Hospital Death Record Review.** Pursuant to 45 CFR Section 164.512(h) and Tex. Health & Safety Code Ann. Section 241.153(h), as amended, LifeGift is hereby authorized to review Hospital's death records, pursuant to section 3.5 herein, with the purpose of furthering the Hospital's quality assurance programs and facilitating organ and/or tissue donation and transplantation. LifeGift agrees that: (i) it shall not use or disclose Hospital's death records or patient's health care information for any purpose other than for quality assurance or to assist in the delivery of health care services related to organ and/or tissue donation; and (ii) it shall take appropriate steps to protect the confidentiality of Hospital's death records and patient's health care information as required by law.

**2.11 Qualified Personnel.** LifeGift will send only qualified individuals to perform donor assessment, evaluation, consent, clinical management, organ allocation, and assistance with surgical retrieval of organs as specified in 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.

**2.12 Management of Potential Donor Organs and Tissues.** Following pronouncement of brain death by an appropriate practitioner, LifeGift personnel as specified in 2.11 shall assume responsibility for donor management in order that the potential donor is maintained in a manner that maintains the viability of the organs. LifeGift staff shall record orders in the chart for necessary treatment and diagnostic testing of the donor, a deceased individual, in order to determine and maintain organ suitability. LifeGift's duties shall include, but are not necessarily limited to, the following activities with regard to testing and recovering potential donor organs and tissues and maintenance of patient records and health information.

**2.12.1 Donor Evaluation.** LifeGift shall be responsible for evaluation of potential donors and will comply with federal Organ Procurement and Transplant Network (OPTN) regulations.

**2.12.2 Laboratory Testing.** LifeGift shall be responsible for obtaining the appropriate laboratory testing of donors as required by applicable federal and state laws and regulations. All costs of testing shall be the responsibility of LifeGift.



**2.12.3 Diagnostic Testing.** LifeGift shall be responsible for obtaining the appropriate diagnostic tests such as echocardiograms, bronchoscopies, sonograms, biopsies, etc., in order to assess organ function. All costs of testing shall be the responsibility of LifeGift.

**2.12.4 Donor Clinical Management.** LifeGift shall be responsible for maximizing the potential donor's oxygenation and perfusion status through ventilatory management and administration of fluids and medication.

**2.12.5 Donor Organ Retrieval.** LifeGift shall be responsible for arranging the operating room time and the arrival/departure logistics for recovery teams from transplant programs who have accepted an organ. LifeGift will coordinate requests from the multiple teams involved in recovery and determine which can be accommodated.

**2.12.6 Transfer of Potential Donor.** If for any reason Hospital does not have an operating room available and one cannot be provided in a timely fashion as determined by LifeGift without jeopardizing the viability of an organ or tissue, LifeGift may transfer the potential donor to another facility for recovery of the tissue(s) or organ(s) at LifeGift's expense.

**2.13 Cooperation with Hospital.** LifeGift agrees to cooperate fully with Hospital in the performance by Hospital of Hospital's responsibilities under this Agreement and federal and state laws.

## ARTICLE III

### Responsibilities of Hospital

In accordance with Title XI of the Social Security Act, as amended, and the Texas Anatomical Gift Act, as amended, Hospital shall have the following responsibilities:

**3.1 Cooperation with LifeGift.** Hospital agrees to cooperate fully with LifeGift in the performance by LifeGift of LifeGift's responsibilities under this Agreement and federal and state laws.

**3.2 Establishment of Donor Program.** Hospital shall establish a donor program to aid in the referral of potential organ and tissue donors to LifeGift. At a minimum, Hospital agrees to the following with regard to its donor program:

**3.2.1 Notification Procedure.** Hospital shall establish a procedure for notifying LifeGift whenever a patient reaches the criteria for imminent death or cardiac death. Hospital shall timely notify LifeGift of *all* hospital deaths as required by law.<sup>1 2</sup> Hospital shall call the LifeGift referral line (see section 2.1) or inform the LifeGift Coordinator (see section 3.2.5) in person, if the coordinator is located in the Hospital. Hospital agrees to designate health care professionals available 24 hours per day to make a timely referral to LifeGift if there is any imminent death or cardiac death in the Hospital.

**3.2.2 Maintenance of Potential Donors until and during LifeGift Assessment Period.** After referral of the potential donor to LifeGift and until LifeGift is able to assess the donor for medical suitability, measures necessary to ensure the medical suitability of the potential donor may not be withdrawn unless the hospital or

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<sup>1</sup> Hospital is not required to report abortions, miscarriages or fetal deaths, except for those issued death certificates.

LifeGift knows that the individual expressed a contrary intent, as established in Section 692A.014(c) of the Texas Health and Safety Code.

**3.2.3 Protocol for Determining Death.** Hospital shall establish a protocol for determining when death occurs, which shall include brain death criteria established by Texas law.

**3.2.3.1** Hospital shall ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable time frame for organ viability.

**3.2.4 Patient Information.** Hospital shall provide LifeGift with appropriate patient information, including, but not limited to, name and time of death, medical and social history, and the medical record, as authorized by Section 241.153(5) of the Texas Health & Safety Code and 45 CFR Section 164.512(h).

**3.2.5 Hospital Documentation.** Hospital shall document all patient deaths and subsequent donor referrals by using a Routine Notification of Death form mutually acceptable to both Hospital and LifeGift. Additionally, LifeGift and/or Hospital shall complete a Donation Consent form to accompany the Routine Notification of Death form in the event that consent for donation is given by persons legally authorized to make donations on behalf of patient. Hospital shall include the Routine Notification form and Donation Consent form as applicable in the patient's medical record.

**3.2.6. LifeGift Coordinator.** If appropriate, based on the volume of potential donors in the Hospital, Hospital and LifeGift may agree to the placement of a LifeGift Coordinator in the Hospital to assist hospital in establishing and maintaining an effective donation program.

**3.3 Hospital Duties in Assisting the Recovery of Organs from Potential Donors.**

**3.3.1 Physiological Support of the Potential Donor.** Hospital shall perform appropriate donor maintenance pending the recovery of organs and/or tissues pursuant to guidelines provided by LifeGift.

**3.3.2 Credentialing.** LifeGift will send only qualified, trained individuals to perform donor management and organ recovery as represented in 2.11. This fulfills JCAHO and CMS requirements, making it unnecessary for the hospital to grant clinical privileges to LifeGift. See addendum 1.

**3.3.3 Asystolic Recovery.** Hospital has in place a donation policy that includes provision for asystolic organ recovery (commonly referred to as "Donation after cardiac death" or DCD donation)

**3.3.4 Provision of Operating Room Space.** Hospital shall provide appropriate space in the Hospital for organ and/or tissue recovery, on terms agreeable to both LifeGift and Hospital. LifeGift retains the option to transfer a potential donor to another facility for organ and/or tissue recovery if, in LifeGift's reasonable judgment, Hospital does not have an operating room available and one cannot be provided in a timely fashion without jeopardizing the viability of an organ or tissue. The transfer will be accomplished at LifeGift's sole expense.

**3.4 Donor Documentation.** Hospital shall in cooperation and conjunction with LifeGift, complete and maintain documentation for requests and/or consents relating to organ and/or tissue donations.

**3.5 Quality Assurance.**



**3.5.1 Death Record Review.** Hospital shall permit LifeGift to conduct periodic reviews of inpatient death records and patient charts to determine compliance with applicable laws and regulations and with Hospital policy regarding organ and tissue donation. Pursuant to 45 CFR Section 164.512(h) and Tex. Health & Safety Code Ann. Section 241.153(h), as amended, LifeGift is hereby authorized to review Hospital's death records pursuant to section 3.5 herein, with the purpose of furthering the Hospital's quality assurance programs and facilitating organ and/or tissue donation and transplantation. LifeGift may use or disclose Hospital's death records or patient health information for purposes provided in this Agreement or as required by applicable laws.

**3.5.2 Organ Procurement Effectiveness.** Death referral and conversion rate data, among other indicators developed jointly with the designated OPO (e.g. appropriate/effective requestor rates), are collected, analyzed, made available, and used in collaboration with the OPO to implement strategies to improve organ donation rates in the hospital. The organ, tissue and eye donation program, furthermore, is integrated into the hospital's QAPI program. *(Note: Conversion rate is defined as the number of actual organ donors over the number of eligible donors as defined by the organ procurement organization (OPO), expressed as a percentage.)*

**3.6 Informing the Local Medical Examiner.** Hospital shall inform the local medical examiner or justice of the peace when a death occurs that is within the local medical examiner's or justice of the peace's jurisdiction. LifeGift will provide assistance with medical examiner notification as requested by the Hospital. Notification of the medical examiner does not relieve the Hospital of its duty to refer the imminent death or death to LifeGift.

## ARTICLE IV

### Reimbursement

**4.1 Reimbursement.** As payment for the services provided and the costs incurred by Hospital in the recovery of organs and/or tissues, Hospital agrees to the following reimbursement:

**4.1.1 Reimbursement for the Recovery of Bone and Tissue.** Hospital and LifeGift agree to the flat fees set forth in Exhibit A to be paid to Hospital by LifeGift for the use of Hospital operating room facilities for the sterile recovery of bone and other tissues at Hospital. Other tissues shall include heart valves, saphenous veins and skin.

**4.1.1.1 Responsibilities of Hospital.** Hospital shall accept payment of the flat fees set forth in Exhibit A as payment in full for the use of Hospital's operating room facilities by LifeGift for the tissue recovery procedures. Hospital shall establish an institutional account and appropriate billing procedures mutually agreeable to both LifeGift and Hospital.

**4.1.1.2 Responsibilities of LifeGift.** LifeGift shall reimburse Hospital for the use of Hospital's operating room facilities according to the flat fees set forth in Exhibit A. LifeGift shall provide all personnel, equipment and supplies necessary for each tissue recovery. LifeGift shall thoroughly clean Hospital operating room after each tissue recovery at Hospital.

**4.1.2 Reimbursement for the Recovery of Organs.** Costs incurred by Hospital in the recovery of organs shall be reimbursed to Hospital by LifeGift in accordance with Exhibit B, which is attached hereto and incorporated herein in its entirety by this reference.



**4.2 Payment of Reimbursement.** Hospital shall provide an invoice to LifeGift for reimbursement that is required to be paid by LifeGift pursuant to sections 4.1.1 and/or 4.1.2. All payments required to be made pursuant to this Article IV shall be due within 45 days of LifeGift's receipt of the invoice from Hospital.

## ARTICLE V

### Term and Termination

**5.1 Initial Term and Renewal.** This Agreement shall be for a term of one year from the date first set forth above and shall be renewed automatically from year to year unless terminated sooner as set forth herein.

**5.2 Termination.** This Agreement may be terminated by either party with or without cause after one hundred twenty (120) days written notice to the other party via registered mail, return receipt requested, of intent to terminate. LifeGift agrees to notify the Secretary of Health and Human Services in writing if this Agreement is terminated.

**5.3 Acknowledgment.** Hospital acknowledges that hospitals are required under Title XI of the Social Security Act to operate and have an agreement with the Medicare certified OPO in its service area, as defined by the CMS. Exceptions to this rule require the Hospital to obtain a waiver from CMS. In acknowledgment of the public policy expressed by CMS in its rules, Hospital and LifeGift agree to communicate any issues related to the relationship created by this Agreement and agree to cooperate to resolve any issues prior to the Hospital's applying to CMS for a waiver.

## ARTICLE VI

### Relationship of the Parties

**6.1 Independent Contractor.** The relationship between the Hospital and LifeGift shall be that of an independent contractor. The parties agree that none of the provisions of this Agreement is intended to create, nor shall be deemed or construed to create, any relationship between the Hospital and LifeGift other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. It is expressly agreed that the Hospital and its personnel shall not for any purpose be deemed to be an employee, agent, partner, joint venturer, ostensible or apparent agent, servant or borrowed servant of LifeGift and that LifeGift and its personnel shall not for any purpose be deemed to be an employee, agent, partner, joint venturer, ostensible or apparent agent, servant or borrowed servant of Hospital.

**6.2 Indemnification by Hospital.** The Hospital hereby agrees to indemnify and hold harmless LifeGift and all of its directors, officers, employees and agents from all suits, actions, claims, or cost of any character, type or description brought or made on account of any injuries, death, or damage received or sustained by any person or persons or property, including patients, arising out of or occasioned by any acts of negligence of Hospital or Hospital's agents or employees whether occurring during the performance of the services hereunder or in the execution of the performance of any of its duties under this Agreement.

**6.3 Indemnification by LifeGift.** LifeGift hereby agrees to indemnify and hold harmless Hospital and all of its directors, officers, employees and agents from all suits, actions, claims, or cost of any character, type or description brought or made on account of any injuries,

death, or damage received or sustained by any person or persons or property, including patients, arising out of or occasioned by any acts of negligence of LifeGift or LifeGift's agents or employees whether occurring during the performance of the services hereunder or in the execution of the performance of any of its duties under this Agreement.

## ARTICLE VII

### Miscellaneous

**7.1 Access to Books and Records.** Hospital recognizes that the CMS requires that persons and entities that provide services to health care providers maintain records reflecting the costs associated with such services. Therefore, Hospital agrees to allow the Comptroller General of the United States, the Department of Health and Human Services, and their duly authorized representative's access to Hospital's books, documents, and records until the expiration of four (4) years after the services are furnished under this Agreement. The types of records covered by this clause, the persons entitled to access, and the manner in which the records may be requested and reproduced shall be governed by 42 CFR 420.300-420.304, as amended from time to time (the "Regulations"). The sole purpose of this paragraph is to comply with the Regulations. This paragraph shall not be interpreted to require Hospitals to provide access to its records or to any persons or entities, other than those set forth in the Regulations. Subsequent amendments to or repeal of the Regulations shall be deemed to govern the obligations created in this paragraph as of the effective date of amendment or repeal.

**7.2 Confidentiality of Protected Health Information.** LifeGift acknowledges the importance of the confidentiality of protected health information as that term is defined by the regulations and accountability implementing the privacy and security standards under the Health Insurance Portability Act of 1996 ("HIPAA"), 45 CFR § 160.103. LifeGift shall protect the confidentiality of protected health information to the extent required by law. LifeGift is not a covered entity under HIPAA. Both parties acknowledge that the privacy standards, 45 CFR § 164.512 (h) state: "A covered entity may use or disclose protected health information to organ procurement organizations . . . for the purpose of facilitating organ, eye or tissue donation and transplantation." The U.S. Department of Health and Human Services has explained that it is not necessary to have a business associate agreement between a covered entity and an OPO.

**7.3 Notices.** Any notice required to be given pursuant to the terms of this Agreement shall be in writing, and shall be delivered personally or mailed, postage prepaid, by certified mail, return receipt requested, to LifeGift or Hospital at the address of the party to which such notice is being sent indicated below the signature of such parties. Either party may change such address by giving notice to the other party as provided above. The notice shall be effective upon receipt by the person to be notified.

**7.4 Assignment.** The Hospital shall not assign or transfer its rights, duties or obligations under this Agreement without the prior written consent of LifeGift. LifeGift shall not assign or transfer any or all of its rights, duties, or obligations under this Agreement without prior written consent of the Hospital. No delegation of any duties by the Hospital or LifeGift shall relieve the Hospital or LifeGift of responsibility for their performance under this Agreement.

**7.5 Severability.** In the event that a provision of this Agreement is rendered invalid or unenforceable for any reason, the unenforceability thereof shall not affect the remainder of this Agreement, which shall remain in full force and effect and enforceable with its remaining terms.

**7.6 Exhibits.** All exhibits referred to in this Agreement are attached hereto and incorporated herein by reference.