

CONTRACT FOR DONOR SERVICES

The parties to this contract are Collin County Medical Examiner, located at 700 B. Wilmeth Road, McKinney, Texas 75069 hereinafter referred to as "Medical Examiner") and The University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, Texas 75390, on behalf of its Transplant Services Center (hereinafter referred to as "UT Southwestern TSC").

RECITALS

WHEREAS, the parties have been cooperating to facilitate the procurement of tissues and eyes for transplantation under an informal Memorandum of Cooperation;

WHEREAS, the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services (hereinafter referred to as "CMS") Conditions of Participation for Organ Donation which set forth its policies governing organ, tissue and eye donation;

WHEREAS, the CMS policies necessitate the clarification of issues contained in the previously executed Memorandum of Cooperation between the parties; including organ eye, and tissue;

WHEREAS, the parties wish to more formally set out their respective responsibilities to ensure compliance with requirements implemented by CMS, the Joint Commission (hereinafter referred to as "TJC") and the Food and Drug Administration (hereinafter referred to as "FDA"), and to more clearly outline the unique community-focused services being offered and provided by UT Southwestern TSC.

THEREFORE, the parties agree to act in good faith and with reasonable diligence as follows:

I. RESPONSIBILITIES OF MEDICAL EXAMINER

- A. Comply with all federal and state laws and regulations governing the donation of organs and tissue.
- B. Establish and comply with written policies and procedures concerning organ and tissue donation which includes, but is not limited to, notification procedures, providing information to donor next of kin and requesting permission for donation, obtaining required consent, appropriate maintenance care of donors pending retrieval, and provision of education of MEDICAL EXAMINER staff on all donation issues.
- C. Provide a copy of MEDICAL EXAMINER's written policies concerning organ and tissue donation to UT Southwestern TSC.
- D. Identify and refer all potential tissue and eye donors to UT Southwestern TSC via a shared notification system as prescribed by CMS including notification and statements of intent to all affected or collaborative parties.

- E. Obtain all medical records and medical history information required to assess donor suitability, and provide access to all such records to UT Southwestern TSC.
- F. Assist UT Southwestern TSC, when necessary, in discussing donation options with families of potential donors to ensure that proper request for permission for tissue and eye donation takes place.
- G. Notify medical examiner as appropriate and assist with coordination when necessary.

II. RESPONSIBILITIES OF UT SOUTHWESTERN TSC

- A. Comply with MEDICAL EXAMINER's policies concerning organ and tissue donation, insofar as those policies are not inconsistent with federal and state laws, their regulations and UT Southwestern policy concerning organ and tissue donation and utilization.
- B. Upon notification by an organ procurement agency, its designee or MEDICAL EXAMINER, evaluate donor's medical information, including charts from the emergency room, critical care, or other treating MEDICAL EXAMINER units, to determine suitability for tissue donation. If donor is not suitable for donation, provide referral documentation to the MEDICAL EXAMINER's referral person. If donor is suitable for donation, participate as requested in obtaining consent from the next of kin.
- C. UT Southwestern TSC shall be available to assist the attending physician and MEDICAL EXAMINER staff on issues concerning donor acquisition and graft retrieval, which shall include availability to request or assist with a request for permission for tissue and eye donation from next of kin, and to obtain all pertinent medical/social history information from the next of kin.
- D. Provide instructions to MEDICAL EXAMINER on care of the donor's body for tissue and eye donation.
- E. Make the decision on where procurement will take place, based on the type of tissues to be recovered, autopsy status and facilities available. UT Southwestern TSC will perform the procurement procedures in MEDICAL EXAMINER's pathology facility or other mutually agreed upon space in all cases where operating room facilities are not required, in order to reduce costs and to keep operating room space open for other needs. UT Southwestern TSC maintains its own operating room on site at its retrieval facility, thereby eliminating lengthy use of MEDICAL EXAMINER space. If procurement is to take place at UT Southwestern TSC facilities, UT Southwestern TSC shall be responsible for making transportation arrangements and shall assume the costs.
- F. Conduct the procurement process according to procedures established by UT Southwestern TSC.
- G. Provide follow-up information on tissue disposition to the donor's family and all involved medical personnel as permitted under laws and regulations governing confidentiality of patient records.
- H. Conduct periodic rounds and in-service training as appropriate and at times mutually agreed upon by UT Southwestern TSC and MEDICAL EXAMINER in order to provide

education on tissue procurement, donor identification, acquisition and transplantation. UT Southwestern shall serve as an information resource for all aspects of tissue and eye donation.

I. Comply with applicable federal law and regulations (CMS, HHS, FDA), state laws, standards, rulings, or regulations of Joint Commission on the Accreditation of Healthcare Organizations, and UT Southwestern policy governing organ and tissue donation and utilization, including all accreditation requirements promulgated by the American Association of Tissue Banks and Eye Bank Association of America. UT Southwestern has and abides by a Code of Conduct and Compliance Program that is substantially similar to MEDICAL EXAMINER's Code of Conduct and Compliance Program.

J. UT Southwestern TSC represents that it shall not employ or contract with any individual or entity who is excluded from participation in Medicare or any federal health care program under section 1128 and 1128A of the Social Security Act or as defined at 42 U.S.C. section 1320a-7b (f). UT Southwestern TSC represents that UT Southwestern TSC is not excluded from participation in any federal health care program as defined at 42 U.S.C. section 1320a-7b (f). UT Southwestern TSC shall notify Medical Examiner immediately in the event UT Southwestern TSC is excluded from participating under Medicare or any other governmental program at which time Medical Examiner will have the right to immediately terminate this Agreement.

K. The parties understand and agree that this Agreement may be subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the administrative regulations and/or guidance which have issued or may in the future be issued pursuant to HIPAA, including but not limited to the Department of Health and Human Services regulations on privacy and security, and Texas state laws pertaining to medical privacy (collectively, "Privacy Laws"). The parties agree to comply with all Privacy Laws that are applicable to this Agreement and to negotiate in good faith to execute any amendment to this Agreement that is required for the terms of this Agreement to comply with applicable Privacy Laws. In the event the parties are unable to agree on the terms of an amendment pursuant to this paragraph within thirty (30) days of the date the amendment request is delivered by one party to the other (the "Renegotiation Period"), this contract may be terminated by either party upon written notice to the other party.

L. UT Southwestern TSC shall, upon request, respond to all calls received from the MEDICAL EXAMINER regarding the outcome of the referral.

M. Provide education to MEDICAL EXAMINER twice yearly or as requested by MEDICAL EXAMINER.

N. Provide routine donor activity and statistical data to the MEDICAL EXAMINER.

O. Use discretion and sensitivity in all MEDICAL EXAMINER and donor family interactions.

P. Utilize to the best of its ability FDA, AATB, and EBAA regulations and standards in the determination of donor suitability.

Q. Offer donation for transplantation only when transplantable suitability guidelines appear appropriate and make clear when research and teaching are the more likely outcomes for the donation.

III. ADDITIONAL AVAILABLE SERVICES

As a full-service tissue bank, UT Southwestern TSC has the unique capability to offer additional, specialized services which can be arranged when requested by MEDICAL EXAMINER. In addition, UT Southwestern TSC has made a commitment to the return of transplantable tissues to the local community. UT Southwestern makes available the following special services:

- A. UT Southwestern TSC will provide UT Southwestern TSC contracted hospitals in Collin County with autograft storage for such tissues as skull flaps, skin and parathyroid.
- B. UT Southwestern TSC will make emergency deliveries to UT Southwestern TSC contracted hospitals in Collin County for its unanticipated needs for bone, skin and cornea transplants.
- C. UT Southwestern TSC will maintain an inventory of regularly required high-demand allografts for UT Southwestern TSC contracted hospitals in Collin County.
- D. UT Southwestern TSC will provide consultation, design and maintenance of special grafts of limited demand which meet individual physician requirements (e.g. fascia loops, pediatric heel pieces, thumb cartilage) for UT Southwestern TSC contracted hospitals in Collin County.
- E. UT Southwestern TSC will provide policy and audit consultation service to UT Southwestern TSC contracted hospitals in Collin County for the purpose of compliance with the FDA and TJC recommendations and regulations.
- F. UT Southwestern TSC will provide inventory management services to minimize graft loss from expiration under separate contract for grafts provided by TSC for UT Southwestern TSC contracted hospitals in Collin County.

IV. PROCUREMENT COSTS

All direct costs reasonably incurred by MEDICAL EXAMINER which are related to tissue and eye donation to UT Southwestern TSC shall be reimbursed by UT Southwestern TSC to ensure no charges associated the donation are billed to the donor family. Such costs include the following:

- A. Donor maintenance costs related specifically to tissue donation
- B. Donor evaluation (including copies of charts requested by UT Southwestern TSC)
- C. Operating room and associated costs, if any.
- D. Pathology and/or radiology costs associated with testing requested by UT Southwestern TSC for eye and tissue donation.

Invoices shall be sent to:

The University of Texas Southwestern Medical Center

Transplant Services Center
Attn: Office of the Director
5323 Harry Hines Blvd.
Dallas, TX 75390-9074

MEDICAL EXAMINER agrees that in no case shall a donor's family receive a bill for services specifically related to donation or procurement costs.

V. LIABILITY

Neither MEDICAL EXAMINER nor UT Southwestern shall, by entering into and performing its responsibilities under this Agreement, become liable for any existing or future obligations, liabilities or debts of the other party. To the extent authorized by applicable State or local law, each party shall assume responsibility and liability for its own employees while performing the responsibilities under this Agreement.

VI. DONOR RECORDS

All donor records pertaining to the provision of services by UT Southwestern TSC under this Agreement shall be and shall remain the property of MEDICAL EXAMINER; provided, however, such records shall be reasonably made available for use by UT Southwestern TSC upon UT Southwestern TSC delivering to MEDICAL EXAMINER a signed written consent for the release of such records or information. Any records released will be kept confidential according to Texas law.

VII. USE OF NAMES

Neither party will use the name of the other party, the names of the other party's employees or the other party's logo for any purpose without the prior written consent of the other party.

VIII. TERM AND TERMINATION

This Agreement shall become effective upon signature by the authorized representatives of both parties and shall continue for a term of three years. Either party may terminate this Agreement by providing the other with at least sixty (60) days prior written notice.

IX. NOTICES

Any notices required by this Agreement shall be made in writing and given by personal delivery, or by prepaid, first class, certified mail, return receipt requested, or by facsimile, with confirmation of receipt of the facsimile, addressed to the parties as follows:

If to UT Southwestern:

The University of Texas Southwestern Medical Center
Office of Contracts Management

Attn: Shawn Cohenour, Director
5323 Harry Hines Boulevard
Dallas, TX 75390-9062

FAX: 214.648.0845

AND

The University of Texas Southwestern Medical Center
Transplant Services Center
Attn: Office of the Director
5323 Harry Hines Boulevard
Dallas, TX 75390-9074

FAX: 214.648.2086

If to MEDICAL EXAMINER :

Collin County Medical Examiner
700 B. Wilmeth Road
Attn: Dr. William Rohr
McKinney, TX 75069

FAX: 972-548-3760

X. ENTIRE AGREEMENT

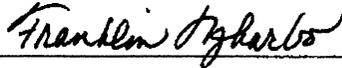
This Agreement constitutes the entire and only agreement between the parties relating to the services being provided hereunder, and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms herein shall be made except by means of a written document signed by the duly authorized representatives of both parties.

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER

COLLIN COUNTY ADMINISTRATION



Peter J. Plantes, M.D.
Vice President for Medical Affairs
Executive Director, Faculty Practice Plan



Name: Franklin Ybarbo
Title: Purchasing Agent

Date

8/18/2011

Date

per 2011-503-08-01