



MEMORANDUM

Date: August 30, 2013

To: The Honorable Chairman and Members
Pima County Board of Supervisors

From: C.H. Huckelberry
County Administrator

A handwritten signature in black ink, appearing to be "CHH", is written over the printed name "C.H. Huckelberry".

Re: **Transplant for Life –Request for Facility License and Fee Agreement for Use of Real Property**

Attached please find correspondence between Dr. Gregory Hess, Pima County's Chief Medical Examiner, and the Transplant for Life (TFL) organization. This correspondence discusses TFL's request for a Facility License and Fee Agreement with the Office of the Medical Examiner relative to organ and tissue donation.

Dr. Hess reviewed TFL's request; and following consultation with the County Attorney's Civil Division, declined the request for the reasons outlined in his May 14, 2013 notification letter to TFL and his August 8, 2013 memorandum to me.

I have reviewed the facts of this matter and all of the information provided by Dr. Hess, as well as that provided by TFL. I fully support the decision of Dr. Hess regarding this matter.

CHH/mjk

Attachments

c: Dr. Gregory Hess, Chief Medical Examiner

**PIMA COUNTY OFFICE OF THE MEDICAL EXAMINER
FORENSIC SCIENCE CENTER**

**2825 East District
Tucson, Arizona 85714**



**Gregory L. Hess, M.D.
Chief Medical Examiner
Department Director**



**Phone (520) 243-8600
FAX (520) 243-8610**

August 14, 2013

**To: John Cover
Tissue Bank Director
Transplant For Life
2230 East Magnolia Street
Phoenix, Arizona 85083**

Re: Reconsideration of Facility License agreement and notification of deaths

I have received your letter dated July 31, 2013. In consultation with the Pima County Attorney's Office and County Administration, I have reviewed your previously declined request to enter into a Facility License agreement with the Pima County Office of the Medical Examiner (PCOME). Following this consultation, the original decision remains the same. The PCOME declines your request to enter into an agreement with Transplant For Life (TFL) to utilize the recovery suite at this facility and forward death notifications to TFL.

The PCOME procedures regarding Organ and Tissue Donation are enclosed as you requested.

Sincerely,


Gregory Hess, MD
Chief Medical Examiner

CC: Chuck Huckelberry, Pima County Administrator

Organ and Tissue Donation

Pima County Office of the Medical Examiner

Forensic Science Center

2825 East District Street

Tucson, Arizona 85714

PURPOSE

This procedure is created to instruct employees or other interested parties in policies and procedures regarding organ and tissue donation at the Office of the Medical Examiner (OME). In addition, this program is designed to comply with the National Association of Medical Examiners inspection criteria for accreditation.

OVERVIEW

The Medical Examiner's Office will actively participate in the implementation of organ and tissue donation following death by authorizing the removal of organs and tissue in accordance with A.R.S. §36-860, release information to the OME designated procurement organization pursuant to A.R.S. §36-861, and follow accepted medical practice. The OME will also take every reasonable step to ensure that organ and tissue removal do not in any way compromise the Medical Examiner's main mission of determining cause and manner of death, the interpretation of wounds or the collection of evidence.

CONSENT/AUTHORIZATION

The OME is often notified of the declaration of death of a potential organ or tissue donor by the hospital or organ/tissue procurement organization (OTPO). In the case of donation after cardiac death, the OME shall be notified prior to death. Medicolegal Death Investigators (MDIs) will notify the OTPO of all deaths reported to the OME for their consideration (A.R.S. §36-861).

The consent may be given by the next-of-kin (per Uniform Anatomical Gift Act; Article 3, A.R.S. §36-848) or by the individual through the Donor Registry (A.R.S. §36-858). After notification has been received the investigator may contact the on call pathologist to ascertain when and if the donation may proceed in complicated cases. Complicated cases are usually defined as cases involving criminal prosecution such as homicides, infant/child deaths, etc. The MDI may approve tissue donation under the authority of the Forensic Pathologist in uncomplicated cases. Depending on the nature of the case the pathologist may release any and/or all organs or tissues based on the medicolegal requirements of the death investigation (A.R.S. §11-594-B-4,5,6). Upon receipt of permission, the OTPO will proceed as per their operating procedure. If the pathologist chooses to limit procurement, the OTPO may compel the pathologist to conduct an examination of the body and provide documentation describing the limitations (A.R.S. §11-594-B-6).

DOCUMENTATION

All documents received from the OTPO will be retained in the chart. In cases in which the heart has been donated for valves, glass slides and the cardiac pathology report generated by the appropriate cardiac pathologist contacted by OTPO to evaluate donor hearts will be sent to the OME pathologist who performed the examination for review

and inclusion in the case file. If residual cardiac tissues are received, they will be properly disposed of as per OME protocol at the discretion of the pathologist. The cardiac pathology report received with the heart will be retained in the chart as per the record retention schedule.

ORGAN/TISSUE PROCUREMENT ORGANIZATIONS

Multiple tissue recovery organizations operate in Arizona procuring postmortem tissues for transplant and research with the permission of donor families. The OME currently forwards preliminary notifications of deaths to a single OTPO for their consideration to contact family of a decedent in an effort to pursue postmortem organ/tissue donation pursuant to A.R.S §36-861, as previously described. When it meets the needs of the donor family and OTPO, tissues are procured at the OME facility as dictated under a separate contract. If tissue cannot be used for transplant purposes, those death notifications are forwarded from the OTPO to research recovery organizations on a rotating basis as agreed upon between the OTPO and each individual research recovery organization. When the OME determines whether or not to forward death notifications to a particular OTPO, the OME will objectively attempt to select the OTPO whom has the greatest capacity to recover tissue for transplant followed by tissue for research for any given decedent. Additionally, staffing levels must be considered when evaluating requests for death notifications as current staffing precludes maintaining death referral and facility use relationships with more than one OTPO.

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Department Director

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TO: Chuck Huckelberry, County Administrator
FROM: Gregory L. Hess MD, Chief Medical Examiner 
RE: Organ/Tissue Procurement Organizations (OTPO)
DATE: August 8, 2013

As you know, the Pima County Office of the Medical Examiner (OME) notifies OTPO's of deaths reported to the OME according to, and in compliance with Arizona Statute and pursuant to OME procedures (attached). OME Organ and Tissue Donation procedures were created to comply with the National Association of Medical Examiner's accreditation criteria prior to our inspection and accreditation in 2010 and have been updated at least annually since that time.

Historically, OTPO's have come and gone in Arizona and our relationship with these organizations has changed over time. I and some of my staff met with representatives from a new OTPO, Transplant for Life (TFL), on April 25, 2013 where we discussed the use of the OME facility for procurement of postmortem tissues. Following this meeting, and after extensive review by me, OME staff and Pima County legal division, the Facility License was denied (attached letter to TFL, dated May 14, 2013). Subsequently, TFL sent a reply addressed to me with copies to the Pima County Board of Supervisors (attached, dated July 31, 2013) in which they requested a copy of OME procedures and reconsideration of the Facility License agreement. TFL also sent cover letters to board members suggesting lack of impartiality regarding this decision (attached, dated July 31, 2013). Below I list short bullet points concerning the issues surrounding the denial of the Facility License.

- The Pima County Attorney's Office Civil Division believes the decisions made by the OME are in accordance with Arizona Statute and OME procedures.
- The OME does not have adequate staffing nor does the OME have an adequate facility to support multiple Facility Licenses.
- No "undisclosed conflict of interest or area of influence" has played a role in the decision making process.
- There are several subjective statements made within TFL's communications that can be construed as misleading.

Thank you for your time and consideration. I would be happy to discuss these issues further with yourself or any other individual you designate. I have a myriad of supporting documents too cumbersome for inclusion in this letter that I can review in more detail as necessary.



TRANSPLANT FOR LIFE
Enhancing Lives.

(602) 512-3085
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Phoenix, Arizona 85083
info@transplantforlife.org
transplantforlife.org

July 31, 2013

Dr. Gregory Hess
Chief Medical Examiner
Pima County Office of the Medical Examiner
2825 E. District Road
Tucson, AZ 85714

Dear Dr. Hess:

We are in receipt of your letter dated May 14, 2013. We want you to know that we truly appreciate your taking time to respond to us in regards to allowing Transplant For Life (TFL) access to your facility and access to the Preliminary Report of Death notifications. We have carefully reviewed your letter and your decision. In all frankness, your letter has taken us completely by surprise as it is vastly different than what was discussed at the OME's office when we understood that the OME would allow us to participate under the same conditions as Donor Network of Arizona (DNA). So please understand that we are disappointed in your office's new position, yet hopeful that you will come to better understand the work we do, how it will benefit the citizens of Pima County and ultimately reconsider our request.

First as it relates to TFL's ability to service donors and donor families in Pima County, TFL's recovery team has more than 30 years combined experience interfacing with your office, recovering out of your office, and have always been viewed by your office as professionals. TFL is registered with the Food and Drug Administration to recover all of the same tissues that DNA is registered for. We can and do recover the **same tissues** DNA recovers. It is important to note that all recoveries performed at your office will never involve organ recovery (as you know) and therefor, the tissues recovered are the **same** under the FDA registration held by both our organizations. DNA and TFL must meet the same standard set by the FDA and the federal government **does not** promote one organization over another. In fact, the federal guidelines forbid any organization from claiming that they provide safer services because ALL entities engaged in tissue recovery must meet the same high standard set by the FDA (this is a matter of public policy).

In fact, TFL offers a **wider** range of services to donor families as compared to DNA. Since TFL is a sister company to Research For Life (RFL), only TFL can offer a seamless process for families wishing to donate for transplant and for whole body donation. In plain terms, a family that chooses transplant donation with TFL will automatically be accepted as a whole body donor with RFL (if consented to). RFL's Guaranteed Donor Program guarantees a donor and their family that they will be accepted, regardless of their medical history and regardless of how much transplantable tissue is taken by TFL. We are curious to know if your office is even aware that the vast majority of transplant donors are refused by whole body donation organizations because of the decreased usability of the donor after transplantation recovery has occurred. This, is a **true** disservice to the citizens of Pima County. This will never happen with TFL donors. RFL will accept **all** donors that TFL recovers, if the family so chooses. DNA cannot offer this service, and the result is that many families are being left in a lurch to bear the financial responsibility of a funeral or cremation after they have donated such a precious gift. With a single service provider, there is no recourse for families when DNA fails to perform.



TFL's position is simple: a single transplant monopoly that cannot maximize the gift of donation, for both transplant and whole body, does not provide an objective measurable benefit to donor families...period.

As pursuant to ARS 36-861". ARS 36-861 sub-part 2 requires that the OME notify "Any **procurement organization** under procedures adopted by the medical examiner for **coordination** of the procurement of anatomical gifts". Further, ARS 36-841 sub-part 22 defines a "Procurement organization" as:

- (a) *An organ procurement organization.*
- (b) *A tissue bank.*
- (c) *An eye bank.*
- (d) *A storage facility that is licensed, accredited or approved under federal law or the laws of any state to engage in the recovery, screening, testing, processing, storage or distribution of human bodies or parts."*

As you can clearly see, Arizona law allows for the participation of any "procurement organization". As it **affects your office**, a "procurement organization" is a "Tissue Bank" or "Eye Bank". In this regard, both TFL and DNA are **equals under the law** and are not further differentiated in any manner.

Additionally, ARS 11-594 states; *"The county medical examiner or alternate medical examiner shall direct a death investigation, shall determine whether an external examination or autopsy is required and shall: Authorize the taking of organs and tissue sas they prove to be usable for transplants, other treatment, therapy, education or research if all the requirements of title 36, chapter 7, article 3 are met. The medical examiner or alternate medical examiner shall give this authorization within a time period that permits a medically viable donation".*

The UAGA makes it very clear that the OME is to have procedures only for the **coordination** of tissue recoveries, it was not meant to exclude tissue procurement organizations (as defined in ARS 38-841-22) from participation in tissue recoveries or an equal manner.

It is important to note that this is not the first time two transplant entities equally participated in the OME notification process and use of a recovery suite in the OME facility. On September 19, 2007, the Maricopa Board of Supervisors voted unanimously to allow Humanity Eye and Tissue (which was not an AATB Accredited bank) to participate alongside DNA. The Board clearly saw the benefit of more than one recovery organization, understood the law, and voted accordingly. Prior to that, RTI Biologics was also allowed to participate alongside DNA. We are not asking for anything to which the law does not allow, nor are we asking for anything that has not already been done by others before us.

In summation, TFL is requesting reconsideration of our request to receive death notification and facility access as per ARS requirements. We firmly believe that Arizona law is clear in its direction to the OME to work with all "procurement organizations". We firmly believe that we are equal to DNA under Arizona law, and that the offerings of more than one transplant recovery organization is in the best interest of the OME and the citizens of Pima County...and Arizona as a whole. Is it in the public interest to have only one hospital provider? One gas station chain? One family practice physician? One funeral home provider? Diversity is important to the public interest by ensuring that a higher level of service and attention to the public is given.



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We believe that if your office reaffirms its previous position (given this new information) the average person would look at this and seriously question whether or not your office has fairly and impartially considered our request to have access. We do not believe that your office will reaffirm its original position. We believe that reason, common sense, adherence to the law, and a true desire to help the citizens of Pima County will prevail. We are looking forward to a decision that welcomes diversity, offers donor families choices and allows others to see that the OME champions ideals that demonstrate leadership and demonstrate proper stewardship of its cases.

We are respectfully requesting a reconsideration of our request and an official response from the OME's office within 30 days from receipt of this letter. We are also formally requesting a copy of the policies/procedures adopted by the OME (as described in ARS 36-861) that were used in making your decision.

Respectfully,

John Cover, BS, CTBS
Tissue Bank Director

CC: Supervisor Ally Miller, Pima County Supervisor, District 1
Supervisor Ramon Valadez, Pima County Supervisor, District 2
Supervisor Sharon Bronson, Pima County Supervisor, District 3
Supervisor Ray Carroll, Pima County Supervisor, District 4
Supervisor Richard Elias, Pima County Supervisor, District 5

Enclosure: TFL FDA Registration
TFL Brochure
RFL Brochure



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July 31, 2013

Mrs. Ally Miller
Pima County Supervisor, District 1
130 W. Congress 11th Floor
Tucson, AZ. 85701

Dear Supervisor Miller,

Transplant For Life (TFL) is an FDA registered tissue recovery organization based out of Phoenix. We are a sister company to Research For Life, a whole body donation program benefitting medical research and education. Our unified goal is to provide the donors and donor families of Arizona with the ability to donate themselves or their loved ones to our program(s) to enhance lives through transplant, educate physicians and ultimately help find cures for diseases that affect all of us in one way or another.

We are writing you to request a meeting with you and to ask for your office's assistance with a serious matter that we believe currently harms the citizens of your district. We are acutely aware that Donor Network of Arizona (DNA) is not and has not been able to service many donors that were eligible for transplant because they simply did not dedicate the resources to recover them in time. Many eligible donors simply "time out" and the gifts simply go to waste. We at Transplant For Life feel that this is a travesty. To simply allow a single entity to recover transplantable tissues in the State of Arizona is simply not in the best interests of the citizens that entrust us to be the best stewards of such a precious gift.

We have met with the Office of the Medical Examiner for Pima County and all were in agreement in our mission and was assured that a non-exclusive contract would be forthcoming that would allow both DNA and TFL to operate in the same space to best service the large volume of transplant-eligible donors that move through that office. Since our meeting we feel that the Office of the Medical Examiner has not been fair and impartial in administering Arizona Law. We are uncertain of the rationale, but are certain that the application of law by a public entity has not been impartially administered. We feel that there may be an undisclosed conflict of interest or area of influence that may be playing a part in the decision making process.

This is not an unprecedented request. On September 19, 2007, the Maricopa Board of Supervisors voted unanimously to allow Humanity Eye and Tissue to participate in tissue recoveries at the Maricopa OME. In addition, Regenerative Technologies Incorporated (RTI) had been allowed to participate previous to Humanity. We are not asking for anything to which the law does not allow, nor are we asking for anything that has not already been done by others before us.

We most respectfully request that your office evaluate our request and allow us the opportunity to explain our position in person at a meeting time that is convenient to you.

Respectfully,

John Cover
Tissue Bank Director
Transplant For Life

CHH meeting

Enclosures: TFL/RFL Marketing Material
OME Letter date May 14, 2013
RFL Letter dated July 31, 2013

**PIMA COUNTY OFFICE OF THE MEDICAL EXAMINER
FORENSIC SCIENCE CENTER**

2825 East District
Tucson, Arizona 85714



Gregory L. Hess, M.D.
Chief Medical Examiner
Department Director



Phone (520) 243-8600
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 **COPY**

May 14, 2013

To: Martin Navarro
Triage Supervisor
Transplant for Life

Daisy Dueker
Director of Transplant Operations
Transplant for Life

Re: Facility License and Fee agreement for use of Real Property

It was my pleasure to meet you both and Garland Shreves on April 25, 2013 to discuss your letter and request for an agreement to begin utilizing our recovery suite for tissue procurement.

As you know, the Pima County Office of the Medical Examiner (OME) currently releases information pursuant to ARS §36-861, concerning deaths reported to the OME, to Donor Network of Arizona (DNA) for their consideration regarding suitability for tissue harvest for transplant. DNA, in turn, forwards information on potential donors that have been ruled-out for transplant to eligible medical research and education organizations for their consideration. I believe this current arrangement provides the greatest possible benefit for potential donor families, as currently, DNA can provide the widest range of transplant services in Arizona.

Considerable time and effort is expended working with DNA and its procurement staff on training, preparing decedents for procurement, maintaining the recovery suite and surrounding areas, administration, etc. Upon discussion with staff and administration, I believe duplicating these efforts with Transplant for Life (TFL) would not be in the best interests of the County, as it would not provide an objective, measureable benefit for donor families beyond what is already provided through DNA and would create an undue burden on the limited staff at the OME. Nor is TFL a reasonable alternative source for the tissue procurement functions currently carried out by DNA, given the relatively limited functions which TFL is able and licensed to perform.

In summary, the OME does not wish to pursue an agreement with TFL to utilize the recovery suite at this facility for tissue procurement nor forward death notifications to TFL for your consideration. If you believe TFL can offer objective benefits to donor families beyond what is offered by DNA, I encourage you to pursue an agreement with DNA to offer those services.

Very Respectfully,


Gregory Hess, MD
Chief Medical Examiner

 **RECEIVED**
5.15.13