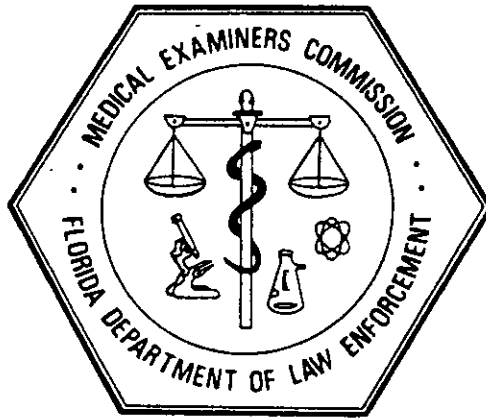




Florida Department of  
Law Enforcement  
James T. Moore, Commissioner



# ETHICAL ADVISORY COMMITTEE REPORT

APRIL 14, 1989

Wallace M. Graves, Jr., M.D.

Joseph H. Davis, M.D. Honorable Jerry M. Blair, J.D. Mr. David P. Farley, L.F.D. Honorable Geoffrey Monge

Oliver H. Boorde, M.P.H. Honorable Douglas M. Midgley Honorable Lee Vause Mr. Arthur C. Wallberg, J.D.



Florida Department of  
Law Enforcement

James T. Moore  
Commissioner

Medical Examiners Commission

P.O. Box 1489  
Tallahassee, Florida 32302  
(904) 488-8090

### ETHICAL ADVISORY COMMITTEE MEMBERS

Paul Watson Lambert, J.D.  
Chairman  
Taylor, Brion, Buker and Greene  
Tallahassee, Florida

Isaac Bruce Koran, J.D.  
Assistant Public Defender  
First Judicial Circuit  
Pensacola, Florida

Theodore Malinin, M.D.  
Director, Tissue Bank  
University of Miami  
School of Medicine  
Miami, Florida

David Smith, Ph.D.  
University of South Florida  
College of Medicine  
Department of Internal Medicine  
Tampa, Florida

Rabbi Warren Kastzl  
Greater Miami Jewish Federation  
Hospice  
North Miami Beach, Florida

E. Charlton Prather, M.D.  
Tallahassee, Florida

*MEDICAL EXAMINERS COMMISSION ETHICAL ADVISORY COMMITTEE*

*REPORT*

Attached to this report, you will find our recommendations to the Medical Examiners Commission regarding the selection of tissue and organ procurement organizations. If attendance at our meetings is any judge, this issue is one of great importance to a number of people. It seems apparent that our recommendations will have some impact beyond Medical Examiner's offices.

Through our deliberations we found that while the number of organizations involved in organ procurement is growing, the individual Medical Examiner has been given virtually no criteria to decide which of several potentially competing organizations to choose.

While organ procurement is important, it remains a collateral aspect of a Medical Examiner's duties. Therefore, we set out to develop recommendations to help the Medical Examiner simplify his responsibilities by limiting the number of organizations with which he or she deals.

Nothing in these recommendations should be taken as an indication that we believe that medical examiners are required to limit the number of organizations. We are simply trying to provide guidelines in the event that they decide to do so.

During our deliberations we learned that not all procurement organizations are organized alike. Some organizations are set up on a not-for-profit basis, while some are profit making organizations. We spent considerable time worrying about the distinction between the two. Because donor families are asked to make donations of organs and tissues without recompense, as philanthropic acts, and because of other ethical considerations, there are restrictions upon what aspects of the procurement and transplantation process may be undertaken for profit.

Distinguishing between not-for-profit and profit organizations, however, was of little help to the committee in attempting to consider the issues above. Those working for all these organizations receive salaries and other remuneration for their efforts. Legally, the important distinction seems to be that not-for-profit organizations are forbidden from paying dividends. We did find it useful, however to distinguish a group of organizations that we call "charitable organizations". These are organizations which finance their operations entirely or largely from means other than fees for products or services. These organizations may use the income from endowments or from various forms of community fund raising to provide products and services at little or no cost to clients. Charitable organizations are to be lauded particularly because they make service to the indigent possible in some communities. It may be useful to distinguish charitable organizations from other organizations and may be wise to give some preference to them so long as in every other way they are effective and efficient in their operations and meet the criteria set forth in the recommendations section of this report.

The committee also spent some time discussing the reluctance of hospitals and procurement organizations to remove organs and tissues for transplant from individuals carrying signed donor cards in the specific absence of specific consent from the next of kin. We urge and encourage hospitals to change that practice. Hospitals and procurement organizations are reluctant to court the possibility of litigation or bad publicity by removing the organ from a card carrying donor without the consent of the next of kin. That means in some cases when a family cannot be reached and in rare cases when a family will not approve the donor's wishes, the organs the decedent had wished to make available for transplant, are not utilized. The failure to use such organs on the part of the procurement organizations and hospitals is inconsistent with the expressed wish of the deceased and, consequently, compromises the individual's autonomy. It further defeats the purpose of the organ donor card statute.

There appear to be various ways to address the problem. The committee did not discuss these in detail. There was some sentiment for legislation which would require the harvest of suitable organs and would forbid the seeking of permission from relatives. There may be additional measures short of additional legislation which would be effective in making sure the wishes of donors are carried out. This question was not directly relevant to the problem presented to the Ethical Advisory Committee, but it did arise in the course of our deliberations. We believed that the Medical Examiners Commission would like to be aware of the issue and our views on the matter.

### RECOMMENDATIONS

1. Making tissues and organs available for transplantation is a laudable aspect of the medical examiner's activity so long as doing so does not interfere with the medical examiner's obligations under Section 406.11, F.S. Individual medical examiners will need to give careful thought as to how their offices will cooperate with the appropriate procurement organizations, in making tissue and organs effectively available and without undo disruption of the efficient ongoing operation of the medical examiner's office. Although it is not unethical for medical examiners to abstain from participating in the procurement of organs and tissues for transplantation purposes, it is desirable that they participate.

2. It is ethical for the medical examiner to select the number of organizations with which his office will cooperate to as few as one to minimize interference in carrying out Chapter 406 responsibilities of the office. Some examiners may wish to make such selections while others may not. The absence of statutes and rules governing procurement of tissues and organs by organizations, places medical examiners in the position of dealing fairly with interested organizations in the public's best interest without the benefit of officially adopted guidelines. The Department of Health and Rehabilitative Services is a logical State agency to regulate procurement organizations and procurement of tissues and organs. These recommendations are offered to guide medical examiners in addressing these issues ethically, until such time as statutes or rules are adopted on the subject. A decision to select should take into account the workload of the office, the nature of the facility and the medical examiner's ability to carry out Chapter 406 responsibilities. We recommend that any decision to select among organizations be on the basis of the following criteria:

(a) The efficient operation of the medical examiner's office. The medical examiner should feel free to create constraints and procedures which will make it possible for the office to operate well and to fulfill its various purposes.

(b) The quality of the operation of the procurement organization. It is an important goal for procurement organizations to be effective in procuring and making tissues and organs available. Occasionally, it is necessary to limit the number of procurement organizations seeking permission to operate within a particular venue to avoid adverse effect upon the efficiency of a medical examiner's office. Any selection process of procurement organizations should assure this goal. Selection criteria should include:

1. Accreditation of the organization by an accrediting organization recognized nationally in the industry, such as the Southeastern Organ Procurement Foundation or The American Association of Tissue Banks, or other similar organizations; *[These credentialing organizations utilize careful examinations and site visits to make sure that the procurement organizations are meeting established standards. The organizations which the medical examiner selects to assist should be accredited by the Department of Health and Rehabilitative Services, in the event the Department of Health and Rehabilitative Services develops accreditation standards for procurement agencies.]*

2. The use of state-of-the-art procedures; *[This implies the reliance on the high standards and the accepted medical practices in the retrieval and processing of organs and tissues for transplantation. This includes both medical personnel involved in transplantation efforts and the facilities in which the work is performed. With regard to the procedures themselves, one might cite the instance of organ and tissue retrieval in the operating room environment using accepted surgical techniques vs. excision of tissues without aseptic precautions.]*

3. The quality of the handling and processing of tissues and organs; *[This implies the adequacy of methodology used in such a manner as to insure the best results with the recipients against untoward effects of organ and tissue transplantation, and to minimize the risk of transmitting disease from the donor to the recipient. The medical examiners who participate in the organ and/or tissue transplantation effort have an inherent ethical right to satisfy themselves with the quality of the effort, and the adequacy of the medical procedures employed in the transplantation of organs and tissues. The medical examiners are not ethically compelled to participate in the transplantation programs which, in their opinion, do not meet the above mentioned criteria. Similarly, if choices have to be made between several organizations involved in organ/tissue transplantation, in the interest of the recipients the medical quality of the program should be a major determining factor in making such a choice.]*

4. The recommendations of the local hospitals and physicians; *[These should be in writing and contain a careful explanation of the reasons why one or more organizations are preferred by the local hospitals or physicians. Such recommendations may shed particular light on the quality of products and services and the use of state-of-the-art procedures.]*

5. Open information about the procurement organization:

a. A list of charges made by the procurement organization; *[The medical examiner may or may not choose to work with the organization with the lowest charges. The provision of information about what charges will ultimately be passed on to the patient served by the organ or tissue should be open and available.]*

b. Use of organs/tissues; *[Information should also be available to the medical examiner and made available to the donors about the true use of tissues and organs. Occasionally, for example, a*

*heart may be procured which cannot be used for transplantation as a whole organ, but the valves may be used. Occasionally, an organ which is donated is not used at all. Information about these results should be made available in summary to the medical examiner and to the family of individual donors upon request.]*

- c. Service to the community; *[The medical examiner may want to consider the following criteria for determination of the quality of service a procurement organization offers a community, in deciding what procurement organization with which to work:]*
  1. A local supply of organs; *[The medical examiner may want to obtain information concerning the degree to which organs which are made available within his community are used within that community as opposed to being sent elsewhere.]*
  2. Service to the medically indigent; *[Transplantation is often an expensive process. Some organizations, notably a group we call "charitable organizations", provide their services for little or no charge, and make special provision to see that the medically indigent have access to the same opportunities for care as are made available to those available to pay. Such concern for the indigent may not necessarily be limited to charitable organizations, however. A charitable organization means an organization described in Section 501(c)(3), Internal Revenue Tax Code, and is exempt from tax under Section 501(a), Internal Revenue Code. Profit and not-for-profit organizations may well have policies that insure that the indigent are served. In as much as medical examiners are public servants, and the medical examiner's office is supported with tax dollars, the medical examiner may want to insure that the organization(s) with which the office works include provision for services to the indigent as a part of their ongoing procedures.]*
  3. Promotion of organ donation within the community; *[The medical examiner may wish to establish how active a particular procurement organization is in promoting voluntary donation within the community. The medical examiner might wish to give preference to an organization which is proactive in promoting the use of donor cards and in soliciting the donation of organs from non-medical examiner cases.]*

4. Other community service; *[The medical examiner may wish to obtain information about other ways in which various procurement organizations serve their community.]*
5. Charitable organizations; *[The medical examiner may wish to give preference to a charitable organization. These are organizations which finance their operations entirely or largely from means other than fees for products or services. These organizations may use the income from endowments or from various forms of community fund raising to provide products and services for little or no cost to clients. Charitable organizations are to be lauded particularly because they make service to the indigent possible in some communities. It may be useful to distinguish charitable organizations from others and may be wise to give some preference to them so long as in every other way they are effective and efficient in their operations and meet the criteria set forth in the previous sections.]*

If a medical examiner decides to select the organizations with which the office will cooperate, it is important that open and fair procedures be used in the decision process. The medical examiner must avoid a conflict of interest, or even the appearance of one, that could occur if he as an individual or any private practice with which he is associated, benefits financially from arrangements with any of the procurement organizations. This ought not to preclude the rendering of appropriate charges to procurement organizations consistent with the providing of organs and tissues for transplants. It is important, however, that both the conflict of interest and the appearance of such conflict be avoided when financial transactions between a procurement organization and the medical examiner or the medical examiner's office are undertaken. Under no circumstances should the medical examiner receive a personal benefit from this relationship.

Appropriate procedures for selecting organizations would include providing an open opportunity to all eligible organizations to provide information relevant to criteria the medical examiner wishes to use in making a decision. Ample notice should be given in sufficient detail about the information required. The various organizations should be reviewed in regard to the criteria specified and the choice be made on a clearly identifiable basis.

That choice should be made promptly and information about it should be open and communicated early. The choice of an organization should be made for a time period sufficient to allow for effective cooperation, but periodic review of that choice is also appropriate. The medical examiner should specify at the outset a time period for which the particular arrangement envisioned will be made.

The overarching goal in all this should be to facilitate the medical examiner's efforts to make available organs and tissues for transplant. Selection of organizations should be undertaken so that the administrative process will not become so complicated that it discourages medical examiners from making transplantable materials available.



Tissue Bank  
 Dept. of Surgery R-12  
 P.O. Box 016960  
 Miami, Florida 33101  
 (305) 547-6465

Theodore I. Malinin, M.D.  
 Director  
 Tissue Bank  
 (305) 547-6786

*From our Tissue Bank*  
*S. O. P.*  
*BCB*

### MEMORANDUM

To: Tissue Bank Personnel and Interested Pathologists  
 From: B.E. BUCK, M.D. and T.I. Malinin, M.D. *BCB*  
 Subj: Autopsies on Bone and Tissue Donors  
 Date: February 1, 1989

The successful transplantation of either vital organs or banked tissues requires, of course, that they be medically safe. It therefore follows that there must be cooperative interactions between the transplant group(s) and the pathologist(s) charged with discovering the medical facts of the life and death of the donor individual.

The post-mortem examination of the donor is clearly the most comprehensive of the several examinations performed to assure the safety of the transplantation allografts. Its exclusionary capabilities are, of course, a manifestation of the fact that it is a thorough examination; indeed are dependent on that thoroughness. The Guidelines for Autopsies which follow stress the importance of thoroughness and timeliness in performing these examinations, and the role of both in the prevention of potential tragedy. In practical terms, the pathologist can rest assured that the Tissue Bank will not release tissue(s) for transplantation until the final autopsy report is available (with the rare exception noted at the end of the first paragraph of the Guidelines). However, the vital organ transplant groups must act in very narrow time frames and the pathologist's phone call can save embarrassment for all concerned.

Following the same line of thought, the question of the pathologist's liability has been raised and an Opinion rendered by the Dade County Attorney. His Opinion is included in this manual of S.O.P. as the next item after the Guidelines for Autopsies.

## GUIDELINES for AUTOPSIES RELATED TO TRANSPLANTATION of VITAL ORGANS and/or BONES and TISSUES

Autopsies of transplantation donors quite properly have unique features, as do autopsies performed for medical-legal reasons, for teaching purposes, and for research. While medical examiners are masters at discovering the sequence of last events, and teachers and students of pathology at putting together the pathophysiology of an illness, the prosector of transplantation donors must be a master of the discipline of thoroughness. He or she has the primary responsibility to prevent the potential tragedy of transmission of disease from a donor to a recipient. It follows then that such an autopsy must be an orderly and thoughtful search for both obvious and subtle disease, followed by timely judgement of all autopsy findings. If a potentially dangerous situation is unfolding, then the appropriate transplant teams must be alerted. Hearts and livers are transplanted 3-10 hours after excision from the donor, kidneys 24-48 hours, and bones and soft tissues after a 3-week minimum. (Rarely some types of soft tissues are transplanted fresh between 49 and 72 hours after excision)..

The scope and magnitude of the task is obvious from two points of view. First, the number of recipients of grafts from a "multiple organ, cornea, bone and tissue" donor is often between 35 and 70. The number will clearly grow much larger in the coming years. Secondly, the recognition of most of the potentially dangerous diseases clearly falls to the pathologist. Clinicians and/or coordinators involved with the evaluation of potential donors screen out all the unacceptable cases they can, depending on the clinical situation. However, many potential donors may have diseases that are substantially subtle or "microscopic only", such as viral myocarditis, a wide range of small cancers, or several neurologic diseases. Consideration of the potential for a major disaster leads to the recognition that only fully-trained pathologists and trainees under the direct supervision of a fully-trained pathologist should be performing these examinations.

**PROCEDURE:** A thorough gross examination is the key to the successful safeguarding of the allografts. The pathologist's oft-quoted admonitions "Medicine is where you find it" and "You can't see it unless you look" are highly relevant to the situation. The gross examination must include multiple cuts of the large organs, opening the bowel and bladder, multiple cuts of the thyroid, pancreas, gonads, pulmonary hilar lymph nodes, etc., and a biopsy of all lesions seen. To exclude those "microscopic only" diseases, it is mandatory to make histological sections of the heart, lungs, liver, lymph nodes, spleen and kidneys from donors of all ages. In some donors of "multiple organs" some of these vital organs will have been excised and not available for examination; however, in these instances the organs will have been evaluated rather thoroughly by clinical means prior to donation.

In view of the epidemic of illness related to human immunodeficiency virus (HIV), pathologists performing autopsies on transplantation donors need to make a special effort to detect and exclude high risk individuals. The transplant/tissue bank personnel will have already excluded all individuals with known high risk behavior (by history), physical signs (such as needle tracts), and/or positive laboratory studies (for hepatitis, HIV-related conditions, syphilis, etc.) But even their best efforts may miss such an individual, and the pathologist has a significant role in assuring the safety of the grafts. The pathologist should make a special effort to section

inguinal, mesenteric, and/or axillary nodes. He/she will, of course, be sectioning the spleen and liver too. The histologic features of nodes which have been related to early HIV infection as well as to unspecified and certain well-known causes include irregularly-shaped follicles, enlarged follicles, follicular mantle effacement, "burnt-out follicles", "follicular lysis", excessive monocytoid cells, excessive plasma cells, presence of epithelial histocytes, presence of polykarocytes (which are multinucleated cells resembling Warthin-Finkeldey giant cells), and vascular proliferation. Only the last three listed are statistically useful in distinguishing nodes from HIV infected persons, but any experienced pathologist has seen each of these features in other clinical settings. Cases with any of these features should be excluded as donors whether or not a specific etiologic diagnosis can be made. The pathologists and the transplant groups must take the point of view that they would rather exclude a few good donors than risk the transmission of disease.

Both gross and microscopic examination of the central nervous system is required for donors over 50 years of age, and for donors of any age with any history of neurological problems. The aid of a neuropathologist may be appropriate in dealing with any neurological problems other than berry aneurysms and hypertensive hemorrhages.

The extreme importance of the microscopic examination is perhaps best shown by a brief review of the reasons we have excluded donors from the last 1000 cases in which the tissues were already excised and the reasons for exclusion were "microscopic only". That is to say, the gross exam suggested the donor was acceptable and the microscopic exam revealed a surprise to all concerned.

- 1) A 20 year-old midwestern white male died of an automobile accident, but also had acute (recently) disseminated histoplasmosis.
- 2) Three men in their 50's and 60's were thought to have died of myocardial infarction but had myocarditis.
- 3) A woman in her 40's died of an intracranial hemorrhage thought to be due to hypertension but it was due to acute meningitis instead.
- 4) Two woman had hepatitis by histologic examination but were negative by the usual battery of serologic studies.
- 5) Two young male donors were excluded on lymph node findings alone (as detailed above) when all serologies and the history were negative.

As with all autopsies, the prosector should save sufficient wet tissue to be able to examine the case in further detail if required or desirable. Case reports still play an important role in the rapidly changing field of transplantation.