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Dedicated to the Restoration of Sight since 1961

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January 21, 2004

Commissioner Carlyle Ring
OBER, KALER
1401 H Street, NW
5th Floor
Washington, DC 20005

**Re: Revision of the 1987 Uniform Anatomical Gift Act
Recommendations to the National Commission on Uniform State Laws
(NCUSL)**

Dear Commissioner Ring and Members of the Commission:

As the national non-profit association of eye bank organizations dedicated to the restoration of sight, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on potential revisions to the 1987 Uniform Anatomical Gift Act (UAGA), and to participate in the process. Established in 1961 by the American Academy of Ophthalmology's Committee on Eye Banks, EBAA member banks are located in 43 states, the District of Columbia, Puerto Rico and Canada. U.S. membership constitutes 99 percent of the entire U.S. eye banking community and provides 97 percent of all corneal tissue for transplantation. Preceding the rest of the transplant arena by decades, the Association has been the primary participant on behalf of transplant over the 35 + year history of the UAGA. Currently, the eye banking community makes it possible to perform more than 46,000 sight restoring transplants annually.

Eye banks have over 50 years of experience in approaching families of deceased loved ones for donation. Not only have eye banks gained experience from years of service, but they have more interaction with families on a routine basis than the organ and tissue community given the criteria for the procurement of eye tissue. Over 90 percent of calls from hospitals are referred to eye and tissue banks for possible donation. Eye banks respond to all these calls and approach donor families according to eye donation criteria which differ markedly from organ and other tissue requirements due to the unique physiology of the cornea and medical indications for transplant.

The number of eye and tissue donors is enormous when compared to donors of solid organs. Approximately 10 individuals donate eye and tissue for every one person who donates organs. Because of our community's role within transplantation and our banks' continued service to patients and their contribution to the prevention of blindness, it is crucial for eye banks to retain their role in the procurement and distribution of corneas and other eye tissue, for transplant.

We have provided a section by section comment to the 1987 UAGA, but want to also comment on policies that have been introduced for consideration or mandated for implementation in the transplant arena in the 35 years since the passage of the UAGA:

- Recovery of tissue: The 1987 UAGA recommended by the NCUSL makes multiple references to the timeliness of recovering certain anatomical gifts, acknowledging "six hours in the case of eyes" as a limitation that makes it necessary to expedite the recovery of this anatomical gift. This is a standard that still holds in eye banking, and the EBAA respectfully requests that this important reference be reinforced in comments accompanying any UAGA revision recommendations made by the NCUSL.
- State Donor Registries and access to donors: All references to donor registries (see section on "Definitions", and others) should be generic, ("state donor registry"). This would benefit all parties to donation and would reinforce the intent of the UAGA. A clear majority of the states with registries have made them accessible to the major procurement organizations. Otherwise, it creates an unequal system, limiting direct access most often for eyes and tissue and confining them to an indirect notice.

With the need for timeliness in the procurement and distribution of eye tissue, it should be clearly stated that access to registries must be equally available to all procuring organizations: OPOs, eye banks, and tissue banks. Eye donation is the most frequent anatomical gift option, and donor eyes must be recovered, as stated above, within six hours of death. Therefore, expedient and direct access to donor registries is necessary for the determination of an individual's recorded consent, limitations, or refusal to donate eyes upon death.

- Organizational relationships: The relationships between hospitals, OPOs, eye banks, and tissue banks should be maintained and respected as direct and individual relationships, unless otherwise agreed to by all parties.
- Hospital protocols for recovery: The development of hospital protocols for donor referrals, staff education regarding anatomical donations, and other activities related to making and facilitating anatomical gifts should be accomplished cooperatively, with the involvement of all entities performing procurements within a hospital. Appropriate

coordination of anatomical donations is only possible with the participation and cooperation of all affected entities.

- Scope of practice of transplant organization: The scope of practice of an individual recovery agency should be defined as limited to its area of expertise. This should reconcile with the professional communities standard of practice, to respect donation and transplantation practice within that specific community. There are three distinct disciplines in post mortem anatomical donation: organs, eyes, and tissues. Each has an area of expertise, and each should have authority within that area.
- State Laws: State laws regarding anatomical donation should in no way discourage or prevent the autonomy and independence of the distinct transplant disciplines.
- Consent. The transplant communities current donation practice affords the donor's family the opportunity to consent on behalf of their loved ones. The requirement of a "social medical history" in recent FDA regulations (21 CFR Part 1270) in particular has promoted the issue as an adjunct to obtaining the donor's behavioral and social profile. Consent is now routinely obtained for the majority of eye tissue provided for transplant in this country.

Medical Examiners Statutes: The issue of consent is subject to interpretation. "Consent" is considered presumptive in the case of so called "Medical Examiners" laws that tie procurement to "no known objection" (of next of kin). Medical Examiners ("ME") laws exist as statutes in more than half of the states, and in practice have either been combined with consent (which obviates the original intent), or more often, not used. When ME laws were first promulgated in 1975 (in the State of Maryland), and thereafter for several decades, the laws made it possible to ensure an adequate supply of corneal tissue for transplant. There has been a significant decline in the use of ME tissue within the eye bank community as consent has gained in importance with the parallel emphasis accorded individual rights.

The 1987 UAGA inserted new language that allowed medical examiners or coroners to release tissue under the ME laws. Since then, several court cases have pitted the state's authority to act under these statutes with an individual's property rights. The outcome has differed and no uniform case law prevails. Therefore, most laws remain on the books, with some in use, particularly in areas of need, such as Puerto Rico. The original intent of these laws was to benefit the public; these laws may again serve a useful purpose should a shortage of tissue occur.

"First Person Consent": This is intended to encourage individuals to express their desire to be a donor. It is contingent on a donor's consent during his lifetime and in some circumstances would "trump" any objection raised by the family (who might not have been aware of this prior act on the part of the deceased). As an organization, we support the concept of "First Person Consent" subject to full disclosure and the adequacy of a

consent that is recorded as a legally binding directive. In addition, this must be combined with a balanced approach in dealing with the donor's family. Sensitivity is key to maintaining the public's trust in anatomical donation.

The practice of many eye banks when confronted with a family that does not wish to donate is to respect the wishes of the family. While current federal policy assumes a working partnership among all entities engaged in donation procurement, it is the role of each organization to use "first person consent", according to policies and practice within their respective organizations

The 1987 version of the UAGA eliminated the category, "*any other person authorized or under obligation to dispose of the body*". It is our assumption that this was considered a "residuary authorization", perhaps a less relevant category than those that preceded it. We would urge reconsideration of including this or some similar, broader category, in the revised Act. Societal relationships have changed significantly in the 25 years following the last UAGA, "Family" has become a fluid concept. Legal partnerships are recognized by law in some states and by practice in others. Patterning this on current societal models would ensure relevance and applicability in coming years.

- Informed Consent: The EBAA recommends full disclosure of relevant information, including any for-profit relationships held by the organizations which request, procure, process or distribute anatomical gifts. These relationships are characteristic in tissue banking and for OPOs that own or have business affiliations with tissue banks for at least two reasons: first, tissues may be "processed" by a for-profit entity following procurement, and second, tissues may be provided in exchange for money to commercial entities. Their subsequent use may be as a commercial product, but they may also benefit the public, and in that sense, be considered a service; there is a need to distinguish between the two.

These activities are not common in eye banking. We think it important to address issues that can be easily misunderstood by the public, and in some cases, abused by those that should be stewards, and distinguish between appropriate and inappropriate actions regarding donation and subsequent use of the gift.

The three national associations which represent anatomical donation efforts, collaborated on an informed consent policy, "*Model Elements of Informed Consent for Organ and Tissue Donation*". The organizations adopted this statement as working guidance to highlight basic elements that are pivotal to achieve "informed decision making" by a family member or other legally authorized person who is being approached for consent to donate. Released in 2000, it is attached with these comments.

- Private Health information: The Association and its member banks take reasonable measures to safeguard all private health information required to facilitate the transplantation of eye tissue. Although neither the EBAA nor its member eye banks are

“covered entities” as defined by the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (“HIPPA”), the EBAA and its members recognize that protecting the privacy of health information is necessary to maintain the public trust and to ensure the integrity of the donation process.

The EBAA supports the maintenance of donor and recipient records as confidential in the absence of express permission to release such information. This permission should reside with the individual who consented to the donation. In the case of first person consent, it should be assigned to the individual’s next of kin as determined through the UAGA hierarchy, in Section 3.

The following recommendations are based on the 1987 model UAGA:

1. Add to Section 1. Definitions:

“Donor Registry” means a mechanism for legally recording an individual’s wishes regarding anatomical donation, in a format accessible at the time of death

“Consent” means an agreement, legally documented, to make an anatomical gift

- a) “Informed Consent” means a decision to make an anatomical gift that is made with consideration of factual, knowledge based information that has been provided to the prospective consenter about the need and purpose(s) for the anatomical gift, the process, applicable commercial disclosures, and other necessary information. At the time of consent, the potential donor must also be given a clear choice to refuse consent, without concern of negative consequences.
- b) “First Person Consent” is a directive of an individual’s intent to make an anatomical donation upon death and recorded in a legally binding manner, in advance of death.
- c) “Next of Kin Consent” means, in the absence of 1 (b), a decision made by an individual who bears a familial relationship with the donor, in the order provided in Section 3.
- d) “Consent by Other Eligible Party” means a decision made, in the absence of 1 (b) or (c), by another party who bears an affinity relationship with the donor or who is responsible for the final disposition of the body

2. Revise definition (12) to read:

“Technician” means an individual who is [licensed] [certified] [trained and qualified] by [the State Board of Embalmers] [an appropriate anatomical gift recovery agency] [an entity that can authorize such an individual] to remove or process a body part.

3. Section 2, “Making, amending, revoking, and refusing to make anatomical gifts by individuals,” (b) include/specify agreement to be listed in a state donor registry as a means by which an anatomical gift can be made and communicated.

4. Section 5. This section describes policies that have largely become obsolete due to federal CMS regulations (Conditions of Participation for Medicare reimbursement, 42 CFR, Part 482, June 22, 1998) (hereafter, “CoP”), which require hospitals to contact an OPO in a timely manner of every patient death or “imminent death.” The CoP also requires hospitals to establish agreements with at least one eye bank and at least one tissue bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes, and to have donation protocols (to educate staff on donation issues, to review death records to improve identification of potential donors, and to maintain potential donors while necessary testing and placement of organs and tissues take place) that include the participation of the banks with which the hospitals have agreements. Hospitals are further required to cooperate to assure appropriate staff education by the recovery agencies, and to designate the individuals (hospital staff and/or recovery agencies) that make the requests for anatomical gifts pursuant to training by the relevant recovery agency (e.g., if the deceased patient is medically suitable to donate eyes, the request may be made by a hospital nurse or an eye bank coordinator who has received training by the eye bank to make such request).

Eye and tissue banks have been very successful to date in increasing donor numbers and access to transplantation. We recognize that the organ community has struggled to do the same and has sought legislative and regulatory assistance to help the community with its mission. As organ, eye and tissue gifts are all impacted by donation policy, the transplant organizations should be expected to participate in the development of public policy on donation, so that no community is inadvertently harmed by efforts to help another community. The EBAA respectfully requests NCUSL support for such involvement as states work to adopt the Commission’s recommended revisions to their respective UAGAs.

The (CoPs) regulation places OPOs in the position of being “default” gatekeepers; that is, if the local eye and/or tissue bank(s) do not have protocols with the hospitals for donor “screening,” then the OPO would, by default, screen for eye and tissue donations as well as for organ donations. The EBAA supports the principle that local agencies should cooperatively determine the functional operations that include donor referral and “screening.” If an eye or tissue bank *elects* to delegate these activities, does so in an atmosphere of mutual cooperation and support, and finds that the subsequently developed systems and protocols successfully meet the bank’s needs, then the EBAA supports such a plan. The EBAA urges the Commissioners to address potential antitrust situations which involve inherent issues of conflict of interest, such as when an OPO owns or establishes an eye or tissue bank, which might provide it with a competitive advantage because of its gatekeeper role.

Eye and tissue banking have been successful activities to date, experiencing increases in donor numbers and access to transplantation. The organ community has formulated many approaches for increasing the number of organs available, without measurable

indicia of success. This further supports the recommendation that no legislative or public policy efforts should be attempted that would cause harm to existing, successful donation systems. In order to assure that this is the case, the eye and tissue banking communities must be actively involved in all aspects of policy- making regarding anatomical donation. The EBAA respectfully requests NCUSL support for such involvement as states work to adopt the Commission's recommended revisions to their respective UAGAs.

5. Section 9. *Please see # 4 above, re Section 5.* The EBAA recommends that the coordination of procurement should be established via policies reflecting its recommendations outlined under this section.
6. Section 11 (a): The EBAA recommends that the statement be revised to read as follows: "An anatomical gift authorizes any examination and testing necessary to assure medical acceptability of the gift for the purposes intended." This adds the element of specificity ("any examination and testing") and at the same time retains the concept of "necessary" to recognize the emerging and continuing examination and testing requirements prior to release of tissue.

The Association appreciates the opportunity to provide comment for your review and consideration. We stand ready and available to assist in this process. I can be reached for questions and assistance at the Association's headquarters in Washington, DC., 202 775 4999, ext. 13.

Thank you for your consideration of our comments and recommendations.

Sincerely,



Patricia Aiken O'Neill, Esq.
President and CEO
Eye Bank Association of America

Attachments

*American Association of Tissue Banks
Association of Organ Procurement Organizations
Eye Bank Association of America*

Model Elements of Informed Consent for Organ and Tissue Donation: Joint Statement

The American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations (AOPO), and the Eye Bank Association of America (EBAA), issued today its “Model Elements of Informed Consent for Organ and Tissue Donation.”

The document was developed collaboratively over the past several months by representatives of the three national organizations, which represent the country’s federally designated organ procurement organizations and most tissue and eye recovery agencies. The leadership of the AATB, AOPO, and EBAA have adopted this statement as working guidance for highlighting basic and additional information elements that are important for informed decision making by a family member or other legally authorized person who is being approached for consent to organ and/or tissue donation.

All three organizations are aware of other initiatives that are in process regarding the matter of informed consent for organ and tissue donation. It is anticipated that this document may be revised in the future as developments warrant.

For further information, contact may be made to Bob Rigney, Chief Executive Officer, AATB (703-827-9582), Paul Schwab, Executive Director, AOPO (703-573-2676), or Patricia Aiken-O'Neill, President and Chief Executive Officer, EBAA (202-775-4999).

November 30, 2000

Enclosure: “Model Elements of Informed Consent for Organ and Tissue Donation”

Model Elements of Informed Consent for Organ and Tissue Donation

Human organ and tissue transplantation has become an important and growing part of modern medical practice. Advances in medical science have made it possible for millions of Americans to receive these life-saving and life-enhancing gifts. None of this would be possible, however, were it not for the tens of thousands of donors and donor families who give their organs and tissues to help their fellow men and women.

The decision to donate must, therefore, be an informed consent, and it must be conducted under circumstances that are sensitive to the consenting person's situation. Information concerning the donation should be presented in language and in terms that are easily understood by the consenting person. The consent should be obtained under circumstances that provide an opportunity to ask questions and receive informative responses. An offer should be made regarding the availability of a copy of the signed consent form, and information should be provided regarding ways to reach the recovery organization following donation. Consent should be obtained in accordance with federal, state and/or local laws and/or regulations. The person seeking the consent should be trained to appropriately answer any questions that the consenting person may have. In addition, coercion should not be exerted in any manner, nor monetary inducement offered to obtain consent for donation. The identification of who may be the appropriate person to consent to donation, and whether the consent of any person in addition to the donor needs be obtained, should be evaluated in accordance with the applicable laws and organizational policy and is not addressed in this statement.

The following list of "Basic Elements of Informed Consent" is intended to highlight the information that may be considered critical to informed decision making by a family member or other legally authorized person, who is being approached for consent to organ and/or tissue donation. This listing, whether communicated verbally or included on consent forms, is not intended to preempt any applicable federal, state, or local laws or regulations that may require more or less information to be disclosed for informed consent to be legally effective.

Basic Elements of Informed Consent

In seeking informed consent, the following information should be provided to the person(s) being approached for consent:

- **A confirmation/validation of the donor's identity and his or her clinical terminal condition.**

Policy Statement on Informed Consent
Page 2

- A general description of the purposes (benefits) of donation.
- Identification of specific organs and/or tissues (including cells) that are being requested for donation (with subsequent information provided on specific gifts recovered).
- An explanation that the retrieved organs/tissues may be used for transplantation, therapy, medical research, or educational purposes.
- A general description of the recovery process (including timing, relocation of donor if applicable, contact information, etc.).
- An explanation that laboratory tests and a medical/social history will be completed to determine the medical suitability of the donor, including an explanation that blood samples from the donor will be tested for certain transmissible diseases.
- An explanation that the spleen, lymph nodes, and blood may be removed, and cultures may be performed, for the purpose of determining donor suitability and/or used to determine compatibility of donor and recipient.
- A statement granting access to the donor's medical records, and that the medical records may be released to other appropriate parties.
- An explanation that costs directly related to the evaluation, recovery, preservation, and placement of the organs and tissues will not be charged to the family.

Policy Statement on Informed Consent
Page 3

- **An explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body.**
- **Any additional information required by federal, state and/or local laws and/or regulations.**

Additional Elements of Informed Consent

In some situations, there may be additional information that should be known by the consenting person(s), or that might be helpful for family decision making. At a minimum, if the donor family inquires about any of these or additional matters, explanations should be provided.

The guiding principle for the use of these “Additional Elements of Informed Consent” is to advance simplicity and reasonableness in seeking informed consent, i.e. include these elements or additional comments if they are appropriate and might clarify any exigencies. For example, if there is the likelihood that the patient will become a Medical Examiner’s case, then it should be appropriate to so inform the family. If it is unlikely that donated tissue is going to be used for aesthetic surgery, then it would not be reasonable to address this issue in the family approach.

One or more of the following elements of information may also be appropriate for communication to the person(s) being approached for consent, depending upon the circumstances surrounding the donation and the potential gift(s):

- **A description of any involvement by the Medical Examiner and/or Coroner, including an explanation that an autopsy may be performed.**
- **An explanation that transplantation may include reconstructive and aesthetic surgery.**
- **A reference to the possibility that the final gift may take a different form than originally recovered.**

Policy Statement on Informed Consent
Page 4

- An explanation that multiple organizations (nonprofit and /or for profit) may be involved in facilitating the gift(s).
- Reference to the possibility that tissue and/or organs may be transplanted abroad

American Association of Tissue Banks

***Association of Organ Procurement
Organizations***

Eye Bank Association of America

November 30, 2000