Do you endorse this draft as is?

No. The Eye Bank Association of America (hereinafter, the “EBAA”), represents 82 eye banks in the United States; our members have daily interaction with coroners and medical examiners in every state. On behalf of these organizations, EBAA cannot support this document as written, and respectfully requests that it be withdrawn.

Donation and the appropriate medicolegal investigation of death are mutually attainable, and EBAA supports the development of best practices to maximize organ, eye, and tissue donation with case by case local decision making for any considerations that might require a restriction. Medical Examiner/Coroner (ME/C) and donation professionals have a history of local collaboration that results in the ME’s accomplishing their goals and lives being saved/function restored for individuals in need. The NAME policy recommendations that we crafted and adopted at the state level all over the country facilitated meeting the needs of the ME/C’s, donors and their families, donation professionals, and recipients. Although well intentioned, the current draft document does not put forth best practices that can be endorsed by all parties, and does not incorporate input from experts in the organ, eye, and tissue recovery community. Due to the specific needs of the ME/C community, perhaps this document would be more acceptable if the document’s points are issued as “guidelines” that can be tailored to suit specific needs of local ME/Cs and their local Organ Procurement Organization (OPO), Eye Bank(s) and Tissue Bank(s) (procurement organizations).

A new process should be instituted to begin developing a true “Best Practices” document for medical examiners/coroners and their interactions with organ, eye and tissue banks; one that reaffirms that organ, eye and tissue donation is attainable without restrictions in virtually every case. The process should be broad-based, transparent, and inclusive of an expanded work group including, but not limited to, donation experts and attorneys with expertise in Gift Law and HIPAA provisions for hospitals, OPOs, tissue banks, eye banks, and health care providers.

As stakeholders, the Eye Bank Association of America and its members look forward to further collaboration with you to further improve this document, and would be willing to serve on your working group as an Honorary member.
Please provide any general comments you have on this draft.

General concerns include:

- Since the eye bank is typically a distinct, separate organization, eye(s) should be added as a reference wherever organ(s) and tissue(s) are used to describe procurement organizations, or when referencing what can be donated;

- Input from significant stakeholders, specifically, organ, eye and tissue donation organizations, was not solicited when developing this document. This has led to serious flaws in this draft that cannot be considered best practices or standards;

- The requirement that OPOs, Eye Banks and Tissue Banks contact medical examiners and coroners before approaching families would be at odds with federal regulations and state UAGA laws. This is a step that should, from a legal and best practice viewpoint, come only after the family has agreed to or been informed of their loved one’s decision to donate through the appropriate state laws regarding donor designation.

- This document does not acknowledge that corneal recovery routinely occurs without destroying physical evidence;

- The draft does not consider the needs of the local ME/C or the procurement agencies with whom they have developed successful protocols specific to their state laws and local needs;

- The National Association of Medical Examiners’ (NAME) “Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation (2006)” is not referenced and should be used;

- Specific language from the revised Uniform Anatomical Gift Act (rUAGA, 2006) is not used even though the rUAGA has become law in most states; it contains “clarification and expansion of rules relating to cooperation and coordination between procurement organizations on the one hand and coroners and medical examiners on the other.” The rUAGA also complies with policy guidelines articulated in the position paper from NAME.

- There is no consideration for individual state laws that address the same issues and there is no reference to a well-constructed HHS/HRSA booklet titled “Death Investigation and Organ and Tissue Donation: A Resource for Organ & Tissue Recovery Agencies, Medical Examiners and Coroners (2006)”;

- There is no indication that this policy seeks a goal of zero denials for donation;

- Federal regulations for healthcare facilities regarding reporting to an organ procurement organization, eye bank or tissue bank of an imminent death or a death (§ 482.45, CMS Final Rule, Condition of Participation: Organ, tissue and eye procurement) must be considered when developing this document; and
• This document fails to acknowledge donor designation and a goal to honor 100% of donor designations. It is inconsistent with donor designation laws, and does not address the practice by eye banks to recover eye tissue from designated donors prior to reaching next-of-kin in order to optimally preserve donor eye tissue.

**SPECIFIC COMMENTS:**

Please list any comments you have on lines 1-12 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

EBAA supports regular communication between organ/eye/tissue procurement agencies and medical examiner/coroners.

Please list any comments you have on lines 15-18 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

We have changed “Standards” to “Best Practices” here. Many OPOs, eye banks and tissue banks have individual agreements with medical examiner/coroners to define specific duties to cooperate in order to maximize the recovery of organs, eyes, and tissue for transplantation. A Best Practice would include a requirement for such an agreement.

Line 15 – 17: Best practice would include the prompt sharing of various reports, including external examinations, toxicology reports, and autopsy findings. We would suggest the following wording:

“Medical examiners and coroners shall cooperate with procurement agencies to maximize the availability of donated organs, eyes and tissues to include prompt sharing of reports (i.e., external examinations, consultations, autopsy reports, investigative reports and toxicological reports) to organ/tissue/eye procurement organizations and tissue processors.

Line 18: To raise awareness, intent regarding time considerations for eye and tissue procurement should reference established professional standards and federal guidelines. Suggest this part to read as follows:

“Tissue and eye procurement shall take place as soon as possible after death with consideration regarding time limits for recovery referenced in US FDA Final Guidance\(^1\) and in professional standards\(^2,3\).”

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1 U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry, Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), dated December 2011.


3 Medical Standards, Eye Bank Association of America, October 2011, Washington, DC.
Please list any comments you have on lines 19-23 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Not requesting donation from a family or honoring donor designation will put an OPO or Eye/Tissue Bank at odds with federal regulations and state UAGA laws, which stipulate that families of all potential organ, tissue, and eye donors must be asked about donation and that every individual has the right to designate anatomical gifts upon death. State laws require OPO/tissue/eye banks to honor legally designated anatomical gifts. In no state does the law expressly allow the medical examiner/coroner to instruct anyone to refrain from making the donation request of families or to ignore the designation of the deceased.

Such actions on the part of the medical examiner/coroner might inappropriately prevent the professional and public discourse between hospital physicians, nurses, donation recovery professionals and the medical examiner/coroner that takes place after a family expresses a desire to donate, when an appropriate balancing of benefits and risks by the medical examiner/coroner may take place.

Further, large metropolitan areas and entire states throughout the U.S. have had zero denials and/or restrictions of life saving organs and life enhancing tissue/eye transplants for decades. The data shows that organ/tissue/eye donation and forensic death investigation can be simultaneously and successfully completed. Therefore, a “Best Practices” document should focus on those successful locations that have this “win-win” joint practice, and endorse a standard of “zero” restrictions, unless specific, objective, examination-based evidence is given pertaining to each organ, eye and tissue system restricted.

The first sentence of this section of the proposed standards should be deleted and reworded as follows:

“The procurement agency shall communicate authorization for eye, tissue, or organ donation with the medical examiner/coroner as soon as reasonably possible after receiving authorization. At their discretion, the medical examiner/coroner can be provided a copy of the Document of Gift or Document of Authorization.”

Please list any comments you have on lines 24-35 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Lines 24-26: The description of the need for performing an external exam and obtaining trace evidence should be reworded to clarify the intent that these functions are to be undertaken by the ME/C or a representative, and there must be an understanding of time constraints related to successful donation. Corneal recovery can occur without destroying physical evidence and may be done prior to the physical exam. We suggest this part to read as follows:

“Communication shall occur with the medical examiner/coroner or their representative so they can arrange to perform an external examination, collect trace evidence, or obtain finger prints prior to procurement (if necessary), however time limits for organ/eye/tissue recovery must be considered.”
Line 27: Regarding body photographs, there are liability, consent, authorization, and local laws that can be related to this task. Eye banks often take photographs only of the face, prior to recovery. We suggest this part to read as follows:

“Photographs of the internal and/or external body may be taken following the direction and written protocols of the ME/C, and following local laws.”

Lines 28-35: The protocol for collecting body fluids or other samples is ME/C specific and there can be concerns regarding unsterile specimen collection that could contaminate tissue donated for transplantation (i.e., drawing vitreous or performing an unsterile cardiac stick prior to recovery). Suggest this part to read as follows:

“Collection of samples (i.e., blood, other body fluids samples, tissue) and sharing of any results should follow the direction and written protocols of the ME/C in cooperation with the organ/tissue/eye procurement organization”

Please list any comments you have on lines 36-43 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Best practices in photographic documentation (and other forms of forensic and medical documentation) and the collection of samples, should be defined by a newly constituted expert panel work group.

Please list any comments you have on lines 44-49 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Best practices in heart valve procurement should be defined by a newly constituted expert panel work group.

Please list any comments you have on lines 50-53 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Best practices in communication of suspicious findings should be defined by a newly constituted expert panel work group.

Please list any comments you have on lines 57-59 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Although the intent of requiring the notification of all living patients referred to OPOs to medical examiners/coroners may be laudable, it is difficult to understand as a practical matter.
These proposed referrals are of patients who are not dead, and may not even fall within the medical examiner’s/coroner’s jurisdiction. The Joint Commission requires hospitals to notify the OPO of mechanically ventilated patients whose death is imminent (TS.01.01.01 EP 9). These referrals are living patients for whom a withdrawal of care is being considered by the family. The vast majority of these many thousands of referrals are not suitable for donation. Requiring hospitals (or OPOs) to call medical examiners/coroners for each of these thousands of referrals of living patients seems to be an overreach of medical examiner/coroner authority, and a great burden without corollary benefit, and should be restricted to pre-mortem notification on cases where the patient: (1) falls within the jurisdiction of the medical examiner/coroner; (2) is medically suitable; and, (3) has given, or the appropriate representative has given, authorization to proceed with DCD.

Please list any comments you have on lines 68-69 of the draft, including any proposed edits you may have. Please include specific line numbers that correlate to your comments.

Best practices should be defined by a newly constituted expert panel work group.

Miscellaneous Comments.

Previous consensus documents appear to have been ignored when writing these standards and best practices. There are examples of various protocols, forms, evidence kits, and information packets in use regionally that have been developed by procurement organizations in cooperation with their local ME/Cs. Gathering a set of these can aid in understanding that ‘one-size’ does not fit all when it involves development of best practices, standards, and guidelines. Many of these can also be found in the HHS/HRSA booklet titled “Death Investigation and Organ and Tissue Donation: A Resource for Organ & Tissue Recovery Agencies, Medical Examiners and Coroners (2006)” and NAME’s “Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation (2006)” We can assist you by providing best practices, if desired.

The impetus behind the “Organ and Tissue Procurement Committee Standards and Best Practices for Interaction Between Medical Examiner/Coroner Offices and Organ and Tissue Procurement Organizations” seems to be that “regular communication between organ/tissue procurement agencies and medical examiners/coroners should occur in order to facilitate continued improvement of processes and to enhance mutual understanding.” This is a positive goal, but the full scope of the federal and state laws governing procurement, the rights of donors, and well-balanced, prevalent true best practices do not seem to have been given consideration.

The proposed “standards and best practices” appear to be intended to “ensure the quality and safety of donated tissues while at the same time ensuring appropriate medico-legal investigation of death,” but the suggested restrictions could facilitate inappropriate, and unauthorized, interference with donor designation and authorization. These proposed standards as currently written do not provide best practices for medical examiner/coroners, and risk putting medical examiners/coroners and procurement organizations afoul of state and federal law, as well as reducing the supply of donated organs, eyes, and tissues for transplantation.
The Eye Bank Association of America (EBAA) and its members look forward to working more closely with the SWGMDI to create a new best practice document to maximize organ, eye and tissue donation while ensuring appropriate medicolegal investigation of death.