OSAC 2023-N-0004 Standard for Interactions Between Medical Examiner, Coroner and all other Medicolegal Death Investigation Agencies and Organ and Tissue Procurement Organizations and Eye Banks

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Medicolegal Death Investigation Subcommittee
Medicine Scientific Area Committee
Organization of Scientific Area Committees (OSAC) for Forensic Science

Draft OSAC Proposed Standard

OSAC 2023-N-0004 Standard for Interactions Between Medical Examiner, Coroner and all other Medicolegal Death Investigation Agencies and Organ and Tissue Procurement Organizations and Eye Banks

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Foreword

This standard addresses relationships and communication among Medical Examiner, Coroner and all other Medicolegal Death Investigation agencies, and organ, eye, and tissue procurement and processing agencies to improve processes and enhance mutual understanding around organ, eye and tissue donation. The following communication standard was developed to preserve the integrity of medicolegal death investigations, while balancing the needs of organ, eye, and tissue procurement and processing agencies, which include quality, safety, transparency, consistency, and timeliness.

The following definitions apply to this document:

the term **'shall'** indicates that a provision is mandatory, and can be audited for compliance.

the term **'should'** indicates that a provision is not mandatory, but recommended as best practice.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

Keywords: medicolegal death investigation, organ donation, organ procurement, tissue donation, eye donation, autopsy, Uniform Anatomical Gift Act, transplant, forensic, coroner, medical examiner, brain death, cardiac death, donation after cardiac death

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Standard for Interactions Between Medical Examiner, Coroner and all other Medicolegal Death Investigation Agencies and Organ and Tissue Procurement Organizations and Eye Banks

1 Scope

This document is a standard for relationships and communication among Medical Examiner, Coroner and all other Medicolegal Death Investigation Offices and organ, eye, and tissue procurement and processing agencies. This document will not specifically address issues that may arise with respect to donation in the context of a mass fatality event.

2 Normative References

There are no normative references. Informative references are included at the end of this document.

3 Terms and Definitions

For purposes of this document, the following definitions apply.

3.1
autopsy
Postmortem diagnostic medical procedure conducted by a pathologist, consisting of external and internal examination of a decedent, and may include other ancillary tests

3.2
biospecimen
Any biological specimen derived from a decedent

3.3
cause of death
Medical opinion of the disease or injury that resulted in a person's death

3.4
chief medicolegal officer
Medical examiner, coroner, justice of the peace, or other official who oversees the operation of a medicolegal death investigation office and/or system

3.5
coroner

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Elected or appointed official responsible for overseeing medicolegal death investigations, usually for a single county, and for certifying the cause and manner of death in these investigations; duties vary based on local enabling statutes

3.6

external evaluation

Physical assessment of the decedent by a medicolegal death investigator

3.7

external examination

Diagnostic medical procedure conducted by a pathologist that consists of physical inspection of the decedent without internal examination; can include ancillary tests

3.8

eye bank (eye recovery organization)

Entity that provides or performs one or more eye banking functions involving ocular tissue from living or deceased individuals for transplantation, research, and/or educational purposes and is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of human eyes or portions of human eyes

3.9

first person consent donors

First Person Authorization makes the indication of an adult's intent to donate some or all organs and/or tissue via a driver's license, a donor card, or other documents legally binding

3.10

forensic autopsy

Autopsy authorized by law and typically performed under the jurisdiction of a medical examiner or coroner for criminal justice, civil, and/or public health purposes

3.11

forensic pathologist

Physician who is board-certified in forensic pathology by an accredited credentialing body; currently American Board of Pathology and American Osteopathic Board of Pathology

3.12

jurisdiction

(1) Legal authority to make legal decisions and judgments regarding a death, including performance of autopsy, as well as investigation and certification of cause and manner of death

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(2) Geographic area in which a medical examiner or coroner's authority applies

3.13

manner of death

Classification system based on the circumstances under which death occurred; usually consists of accident, homicide, natural, suicide, and undetermined. These manners of death are then used for public health and vital statistics purposes

3.14

medical examiner

Appointed forensic pathologist whose duty is to oversee medicolegal death investigations, perform postmortem examinations, and certify cause and manner of death. In some jurisdictions, individuals with other qualifications hold the title "Medical Examiner", but for purposes of this document those individuals are considered medicolegal death investigators

3.15

medicolegal death investigation

Formal inquiry into the circumstances surrounding the death of a human being; investigative information is considered with autopsy findings and adjunctive studies (if performed) to determine the cause and manner of death

3.16

medicolegal death investigation authority

Person or persons whose duty it is to perform medicolegal death investigations for a designated jurisdiction, and ensure certification of cause and manner of death; duties vary based on local enabling statutes

3.17

medicolegal death investigation office

Physical location of an agency (usually a medical examiner or coroner office) with the authority to perform medicolegal death investigations

3.18

medicolegal death investigator

Individual who has completed the requirements for Certification (Registry or Board) by an accredited credentialing body or performs medicolegal death investigations

3.19

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next of kin
Legally determined hierarchy of interested parties who have authority over the decedent

3.20
organ procurement organization (OPO)
Organization that engages in various aspects of organ donation and recovery and supports organ placement within their federally designated service area and the transportation of organs to other regions. An OPO may also function in areas of tissue recovery, tissue banking, eye recovery, and eye banking. The OPO works with transplant centers and the United Network of Organ Sharing (UNOS) to appropriately place organs with patients awaiting a transplant

3.21
tissue procurement organization (TPO) (tissue recovery organization, tissue bank)
Organization that engages in various aspects of tissue donation and is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue

3.22
universal anatomical gift act (UAGA)
One of the Uniform Acts drafted by the National Conference of Commissioners on Uniform State Laws (NCCUSL), also known as the Uniform Law Commission (ULC), in the United States with the intention of harmonizing state laws between the states. The UAGA governs organ donations for the purpose of transplantation

4 Requirements

4.1 Medical Examiner, Coroner and all other Medicolegal Death investigation agencies (MEC/MDI) shall cooperate and communicate with organ, eye, and tissue procurement and processing agencies to facilitate availability of donated organs and tissues. Likewise, organ, eye, and tissue procurement and processing agencies shall work to preserve MEC/MDI evidence to aid in determining cause and manner of death. This may include, but is not limited to, forensic, scientific, and medical information, documentation, and samples/specimens as required for a forensic autopsy and medicolegal death investigation.

4.2 MEC/MDI shall ensure processes are available for sharing information, including referral, for potential tissue and eye donors by MEC/MDI when deaths occur outside of hospitals and other referring institutions.

4.3 The interactions between MEC/MDI and organ, eye, and tissue procurement and processing agencies shall be guided by written agreements/memorandums of understanding (MOU) among the MEC/MDI and organ, eye, and tissue procurement and processing

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agencies.

4.4 Factors to consider when creating an MOU include the standards of the organ, eye, and tissue procurement and processing agencies, recognized medicolegal death investigation guidelines and standards, and any applicable local, state, and federal regulatory authorities.

4.5 This agreement or MOU shall address the following:

a) Procedures for notifying the MEC/MDI or their representative of potential tissue, eye, or organ donation cases falling under the jurisdiction of the MEC/MDI.

b) How the issues of restrictions will be negotiated and resolved.

c) Necessary specimens to be obtained, retained, and documented (including chain of custody issues).

d) Acceptable documentation to include medical imaging, photographs, procedures, and description of the body.

e) Proper authorization for procurement.

f) Handling of next-of-kin communications, to include sequence of next of kin notification of death and eligibility, first person consent, next of kin consent, and MEC/MDI authorization.

g) Location of procurement and resolution of related jurisdiction issues.

h) Transportation of remains.

i) Relevant training and education for both the MDI authority and OPO/TPO.

j) Timing of procurement.

k) Any potential fees, costs or payment.

l) Liability and insurance issues.

m) Privacy and confidentiality concerns.

n) Processes for referral of potential tissue and eye donors by MEC/MDI when deaths occur outside of hospitals and other referring institutions.

o) Resolution of identification issues.

p) Reports and/or residual tissue or specimens from consultations or additional studies.

q) Timeliness of reports.

r) Access to decedent.

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s) Personnel who are the designated liaison or point of contact from each agency.

t) Scenarios in which restrictions may apply.

u) The issue of potential competing contracts for tissue procurement in cases in which an individual dies in a hospital and falls under the jurisdiction of the MEC/MDI.

v) How jurisdiction will be handled in cases of transportation to an organ or tissue recovery center across jurisdictional boundaries, in anticipation of donation after cardiac death.

4.6 Organ, eye, and tissue procurement shall be allowed to take place in an expeditious manner that addresses the needs of both the MEC/MDI and organ, eye, and tissue procurement and processing agencies. Recovery of tissue should occur prior to autopsy, thereby reducing potential for contamination, unless evidence preservation, staffing issues, or other compelling circumstances exist.

4.7 The option of performing an external inspection or examination by the MEC/MDI or their representative shall be provided to the MEC/MDI prior to procurement. Trace evidence may be collected at this time and fingerprints and/or photographs may be taken. Time limits for organ/eye/tissue shall be considered. If requested, the MEC/MDI, or representative, shall be allowed to attend the procurement.

4.8 The MEC/MDI shall request any necessary additional procedures or testing be performed prior to procurement. Examples include, but are not limited to, full body photography, skeletal trauma survey, whole body computed tomography, special laboratory testing, organ biopsy specimens and/or interpretation, and coronary angiogram.

4.9 Samples for toxicological analysis shall be collected by the procurement agency for the MEC/MDI when requested. Such specimens shall be taken in accordance with the MEC/MDI's requested practices and procedures and labeled as to name/unique identifier, date, time and site from which obtained. Blood specimens from the body of the decedent shall include femoral vein blood whenever possible. The procurement agency shall document and notify the MEC/MDI if any drugs, such as papaverine, were used in the procurement process. All agreed upon body fluid samples shall be returned to the MEC/MDI. Admission blood and urine, or samples from the earliest dates in the hospital laboratory shall be reserved for toxicological analysis by the MEC/MDI except for the minimal amount necessary for infectious disease testing by the procurement agencies; this may include agreements to proactively retain samples prior to involvement of the MEC/MDI. Procurement agencies shall share testing results to minimize the amount of blood needed for testing.

4.10 Samples for blood and other cultures shall be collected by the procurement agency for the MEC/MDI when requested. Such specimens shall be taken in accordance with the MEC/MDI's requested practices and procedures and labeled as to name/unique identifier, date, time and site from which obtained.

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4.11 At the time of procurement, detailed notes and photographs shall be taken and provided to the MEC/MDI describing any evidence of injury or disease encountered during the procedure. Any deep venous thrombi or pulmonary thromboemboli encountered shall either remain in situ or be photographed, collected, and submitted with the body to the MEC/MDI. The procurement agency shall notify the MEC/MDI immediately if other abnormalities (such as hemopericardium) are found during the procurement procedure, and await further direction/instruction by the MEC/MDI. Telemedicine / video calls may allow real time intraoperative consultation with the forensic pathologist.

4.12 If whole organs are recovered/procured, such as the heart or kidney, the MEC/MDI shall be provided with a report and potentially photographs and microscopic slides, describing said organs as mutually agreed upon. When requested, the entire remainder of the heart tissue shall be returned to the MEC/MDI for examination. In all other cases the heart tissue shall be referred to a cardiac pathologist of the MEC/MDI's choosing for complete assessment; the expense shall be paid by the TPO. All reports generated shall be routed to the MEC/MDI of record in a timely manner. If any frozen sections, biopsies, or other diagnostic procedures are performed during procurement, a copy of the pathology report shall be provided to the MEC/MDI.

4.13 If an organ is removed and subsequently not transplanted, the non-transplanted organ shall be returned to the MEC/MDI, when requested. If not requested, the disposition of the organ shall be provided in writing to the MEC/MDI.

4.14 If a lesion, suspicious for occult malignancy, infection or other conditions that may affect potential recipients, is discovered during autopsy or external examination, these findings shall be communicated to the organ procurement/tissue agency in a timely manner. This information is vital to those making decisions related to surveillance of organ recipients and to prevent release of unsuitable tissues.

4.15 In cases of declaration of death by circulatory criteria (Donation after Cardiac Death) under MEC/MDI jurisdiction, arrangements are made for rapid procurement of organs after cardiac arrest. The MEC/MDI or their representative shall be notified by the organ procurement organization as early as possible and prior to or upon next of kin consent for donation, so that efficient and timely medicolegal investigation can take place. An effort shall be made to allow the MEC/MDI investigation to occur prior to death pronouncement.

4.16 The goal of MEC/MDI agencies shall be to allow procurement in all cases. Restrictions of individual organs or tissues from procurement shall occur only when procurement of those organs/tissues would impede the investigation of cause of death, destroy physical evidence, or potentially compromise the ability to accurately determine the cause and manner of death; such cases have been reported. Resolution of investigative concerns may be possible to allow for some donation, even if procurement is limited. Some examples of reasonable restrictions of pre-autopsy procurement might include: restriction of skin procurement or organ procurement-related incisions when patterned injuries are present requiring further documentation and examination; lower extremity long bone procurement in pedestrian fatalities with bumper fractures that may aid in identifying a vehicle; specific organ, eye, or skin procurement in child

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abuse or restraint/in-custody deaths; and eye/corneal procurement in strangulation homicides. Skin, bone, and eye procurement would still be possible in most cases following autopsy. Complete denials of procurement should be rare, occurring in complicated and select cases only.

4.17 Regarding first person consent donors, it is important to recognize that these individuals may have special status regarding authorization of procurement. MEC/MDI professionals shall familiarize themselves with the laws in their state of jurisdiction regarding this special case.

4.18 MEC/MDI agencies shall have a policy that proactively addresses and minimizes potential or perceived conflicts of interest regarding relationships with OPO/TPOs. Potential conflicts include but are not limited to secondary employment of an MEC/MDI employee by an OPO/TPO; positions resulting in a personal financial relationship with the OPO/TPO; gifts or monetary donations; or positions of decision-making such as Board of Directors of an OPO/TPO. Advisory roles without compensation are often appropriate, but shall be addressed within individual jurisdictions.

4.19 It may be beneficial for continuing education presentations to be made by MEC/MDI staff to OPO/TPO staff, and vice versa. Topics might include pathologic findings which may be discovered during procurements and be of interest to the forensic pathologist, or the steps required of OPOs prior to procuring organs (which explains timeframes and challenges faced).

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Annex A

Informative References

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