

Shared Protocol for Organ Recovery in Deaths Under Investigation

PURPOSE

The purpose of this Shared Protocol is to support individuals and families seeking to participate in organ donation by establishing a consistent written process for collaboration and communication among Gift of Hope, the federally designated Organ Procurement Organization (OPO), Medical Examiners, Coroners, Law Enforcement, and State's Attorneys when an individual who is or may be under ME/C jurisdiction is also a potential organ donor.

SUMMARY

When an individual is subject to a death investigation, his/her participation in the organ donation process requires careful collaboration among the individual's family, Gift of Hope (the federally-designated organ recovery service provider or OPO), the Hospital and Health Care Providers, State's Attorneys, Medical Examiners and Coroners (ME/Cs), and Law Enforcement Officials. Each of these parties play key roles in ensuring that Illinois patients and families are not unreasonably denied the opportunity to participate in the miracle of organ donation – while also collecting and preserving all available forensic and pathological evidence. Effective cooperation ensures that organ recovery does not interfere with the determination of the cause and manner of death and saves the lives of countless patients in need of organ transplantation. In many cases, organ donation and recovery can provide forensic information that would not otherwise be available in a death investigation. This Shared Organ Recovery Protocol describes how this essential process occurs.

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1. BACKGROUND & COLLABORATIVE GOALS

The scarcity of organs available to save the lives of patients in need has been a recognized public health challenge for decades. As of this writing, over four thousand (4,000) people in Illinois are on the waiting list for a life-saving organ, and another person is added to that list every ten minutes. On average, 18 people across the nation die every day while awaiting an organ that may have saved them.

It has been estimated that as many as 70% of potential donors fall under medical examiner/coroner (ME/C) jurisdiction. Therefore, ME/Cs frequently play a critical role in making organs available for transplantation. Because ME/Cs are also responsible for documenting and collecting appropriate evidence in cases falling under their jurisdiction and determining cause and manner of death, it is essential that the organ recovery occur in a carefully coordinated manner.

In the early 2000s, there was wide variation in ME/C practices regarding the release of potential organ and tissue donors. Some ME/Cs were inclined to deny recovery of organs and/or tissues for transplantation asserting that recovery would interfere with their ability to fulfill their legal mandate: to determine the cause and manner of death, and to ensure that appropriate evidence is collected and preserved. In 2007, the National Association of Medical Examiners (NAME) conducted a detailed analysis of this variation in practice and concluded that, with appropriate communication and cooperation, this should not be the case in the vast majority of situations. In 2014, NAME revisited its prior position and upheld its prior finding that:

> "ME/Cs should permit the recovery of organs and/or tissues from decedents falling under their jurisdiction in virtually all cases, to include cases of suspected child abuse, other homicides, and sudden unexpected deaths in infants. It is recognized that blanket approvals may not be possible in every case, and may require an "approval with restriction(s). ... Some ME/C offices currently have "zero denials" and this should be the goal of every ME/C office."

Other States have adopted legislation to support a collaborative process and have successfully achieved "zero denials" of organs viable for transplant for over a decade.

This Shared Protocol is intended achieve "zero denials" in Illinois without the need for legislation. By establishing a thoughtful collaborative process developed and endorsed by ME/Cs, Law Enforcement, State's Attorneys, and the GOH team, the parties seek to establish a collaborative and cooperative relationship and process that:

- Collects and preserves all available pathological and forensic information
- Supports the fulfillment of statutory or professional obligations to determine the cause and manner of death
- Ensures that Illinois patients and families are not unreasonably denied the opportunity to participate in organ or tissue donation
- Provides accurate information and compassionate care to families who have lost a loved one

- Promotes the recovery of scarce transplantable organs and tissue
- Reduces the number of deaths that occur in Illinois by achieving the "zero denial" status maintained by other States
- Ensures critical information sharing, informed decision making, and efficient use of resources

2. INITIAL OPO & ME/C COMMUNICATION & REVIEW

2.1 Initial GOH & ME/C Communication

Individuals who are eligible to become organ donors are identified when they are hospital inpatients. Typically, the Hospital will notify the ME/C if a potential organ donor may come under the ME/C's jurisdiction. If this has not happened, the GOH ME/C Liaison will contact the ME/C. If the ME/C is informed of a decedent by the hospital, and GOH has not been contacted, the ME/C will contact GOH. The GOH Liaison and the ME/C will establish a communication plan.

2.2 Initial Review of Injuries & Medical Conditions

To ensure the Medical Examiner or Forensic Pathologist has the information available to properly identify the cause and manner of death, the GOH Liaison will provide initial clinical information to the ME/C, including:

- injuries and/or medical conditions documented to date
- testing reports (CT scans, x-ray reports)
- physician admission history/physical exams)

2.3 Discussion with Decedent's Family or Authorized Representative

Determining medical eligibility for organ donation is complex and fact specific. Federal regulations require hospitals to inform Gift of Hope of possible organ donors, and provide Gift of Hope the opportunity to evaluate whether it is appropriate to discuss organ donation with the patient's family members or other authorized representative.

The Gift of Hope team is specially trained to analyze applicable regulatory requirements and the unique circumstances of each potential donor. Gift of Hope will conduct detailed discussions with the potential donor's family or legally authorized representative regarding donation and consult with the ME/C. If the potential donor previously executed a legally binding anatomical gift, additional authorization from the legal next of kin is not necessary to proceed with donation.

Under hospital regulations, individuals who approach families in the hospital regarding organ and tissue donation are required to have specialized training. In most circumstances, the ME/C, law enforcement, and State's Attorneys should defer to specially trained OPO team members and refrain from discussion potential organ donation with family members. Gift of Hope respectfully requests all non-OPO employees to avoid discussing organ and tissue donation with the potential donor family without prior consultation with and/or the presence of the OPO team.

2.4 Consultation with Law Enforcement

Under hospital regulations, individuals who approach families in the hospital regarding organ and tissue donation are required to have specialized training. If Law Enforcement is present at the hospital, the OPO team or the ME/C will request that Law Enforcement officials do not discuss potential organ and/or tissue donation with the potential donor's family. Determining whether organ and/or tissue recovery is possible is a complex case-by-case decision made by the ME/C, working in close collaboration with a forensic pathologist, law enforcement, prosecuting attorneys, and OPO team members.

2.5 Consultation with State's Attorneys

Illinois Statutes provide that the ME/C has the authority to release transplantable organs and tissue to Gift of Hope. If a State's Attorney has any questions or concerns about the preservation of evidence in conjunction with organ and tissue recovery, Gift of Hope has an expert forensic pathologist available to respond.

2.6 Collaborative Conference Call

The most effective way to ensure that all necessary pathological and forensic information is collected and preserved, and accurate information is communicated to the decedent's next-of-kin and other family, is to hold a conference call to discuss the case. Gift of Hope will arrange for the call. Parties to be included on the Case Discussion Conference Call include:

- Bedside Physician & Other Hospital Representatives as requested by Hospital
- State's Attorney (as applicable)
- Law Enforcement (as applicable)
- Child Protective Services (as applicable)
- Gift of Hope Representative
- Coroner or Forensic Pathologist

During the call, the collaborative team will review and discuss the information included on the Procedure Form included as <u>Exhibit A</u>. If the case does not involve potential legal action, Law Enforcement and State's Attorneys are not required to participate.

2.7 Documentation of Findings and Recovery Plan

Gift of Hope will document the substance of the Case Discussion Conference Call and the plan for proceeding with organ and/or tissue recovery, including any specific restrictions on the Procedure form included as <u>Exhibit A</u>.

3. PLAN FOR COLLECTION & PRESERVATION OF INFORMATION & EVIDENCE

For each individual case, the OPO team and ME/C will cooperate to implement the Collaborative Organ & Tissue Recovery Procedure which details how certain information and evidence will be documented, collected, and maintained. See <u>Exhibit A</u>.

4. INDEMNIFICATION

Illinois Statutes currently provide immunity for individuals who act or attempt in good faith to support organ and tissue recovery.

Exhibit A Collaborative Organ & Tissue Recovery Process for Medical Examiner/Coroner Cases

(to be completed by the Gift of Hope team)

Со	ontact Information				
1.	Decedent Information				
	Name:	Date of Birth:	Age:	Gender:	
	Initial Clinical Information (brief	summary)			
2.	Coroner/Pathologist Information				
	Coroner:	Contact Info:			
	Pathologist:	Contact Info:			
3.	Decedent Next of Kin or Legal Re	presentative			
	Name:	Relationship:	Contact Info:		
4.	Hospital Information				
	Hospital:				
	Attending Physician:	Contact Info:		_	
	Primary Nurse:	Contact Info:			
5.	Gift of Hope Information				
	Gift of Hope Representative:	Contact I	nfo:		
	ME/C Liaison:	Contact Info:			
6.	Law Enforcement Information pl	ease provide name of law enforcement	officer handling the case	e (if known and available):	
	Location of Incident (city and count	y, if known):			
	Investigating Agency (if known):				
	Name:	Contact:			

Collaborative Conference Call Discussion

Conference Call Numbers: 1-800-216-6327, Participant # 511347

1.	Date & Time:		
2.	Participants' Names	Agency	Role
3.	Summary of Medical Findings		
•••		γ, physical exam, injuries and/or medical conditi	ons documented to date and completed
4.	External Examination (describe plans	for external examination in the lines b	elow)
	the ME/C or forensic pathologist to perform ar perform the external examination prior to orga a GOH-contracted and ME/C-approved forensic contracted forensic pathologist for his/her serv	cuss the external examination. The Gift of Hope of external examination prior to organ or tissue re an/tissue recovery, at the request of the ME/C, the c pathologist to perform the external examination vices. If the Gift of Hope Representative or the set of Hope Representative will ensure that the ME ucted by the ME/C.	covery. If the ME/C is not available to the Gift of Hope Representative will arrange for on prior to recovery. GOH will reimburse the urgical team participating in organ or tissue

	ohs plogist may request photographs of the decedent in conjunction with the external examination prior to organ Hope Representative will help facilitate a pre-recovery photographs upon request by the ME/C or forensic
	re and the ME/C or forensic pathologist will discuss pre-existing biological specimens and testing previously
	epresentative will facilitate the additional specimen collection/testing as requested by the ME/C.
Serological	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
Histological	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
Other Tissue	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
Vitreous Fluid	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
Urine	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
Other	No additional collection/testing requested
	Requested testing or specimens (<i>describe</i>):
The Gift of Hope Representativ	eports (e.g., bronchoscopy, radiology, CT, MRI) re will ensure that the ME/C has copies of all requested hospital imaging and diagnostic reports. The Gift of tate additional imaging/diagnostics as requested by the ME/C.
No additional imaging	g/diagnostics requested
Requested imaging/o	diagnostics (<i>describe</i>):
The Gift of Hope Representativ request by the ME/C or forensi ME/C, the Gift of Hope Represe examination prior to recovery. Representative or the surgical f	Scheduling of Organ Recovery e and the ME/C will discuss the internal examination. The Gift of Hope Representative will facilitate any c pathologist to perform an internal examination prior to organ or tissue recovery. Upon request by the entative will arrange for a GOH-contracted and ME/C approved forensic pathologist to perform the internal GOH will reimburse the contracted forensic pathologist for his/her services. If the Gift of Hope team participating in organ or tissue recovery observe any internal injuries, the Gift of Hope Representative rensic pathologist is aware and photograph and document the injuries as instructed by the ME/C.

9. Preservation of Lines

If the ME/C intends to examine the decedent after recovery, when the recovery procedure is complete, all vascular access lines and other therapeutic appliances attached to the donor should be left in place. Those lines/appliances that have been inadvertently discontinued should have the insertion site circled and marked with an "Rx," indicating the site as a therapeutic intervention.

10. Recovery Team Reports

The Gift of Hope Representative and the ME/C or forensic pathologist will discuss any ME/C or forensic pathologist will discuss any requests for operative or other written reports from organ recovery transplant surgeons and/or tissue recovery teams.

Organ Operative Report

No, an operative report is not required unless the recovering transplant surgeon notes unusual pathology or injury

____ Yes, GOH to arrange for organ recovery operative reports from each recovering surgeons

GOH will arrange for a formal, typewritten original of the recovery of **each** thoracic and/or abdominal surgeon's "Operative Report to Supplement Autopsy Report" will be forwarded to the Coroner's office in a timely fashion. This report is intended to be filed in the permanent file of the deceased. The operative report will be signed by the recovery surgeon(s) and include the following information:

- Identification of the donor with hospital/medical record number
- Date, time, and name of physician pronouncing death.
- Brief clinical history and evaluation as a suitable donor.
- Pre-operative condition of the area of the body that is involved in or impacted by the organ recovery.
- Names of all surgeons involved in the recovery.
- Description of abdominal and/or thoracic conditions including any preexisting injuries within the site of dissection.
- Description of each organ recovered as normal, or specify any abnormalities.
- General statement of the operative procedure and the condition of the body after the organ recovery is completed.

Bone/Tissue Recovery Report

____ No, an bone/tissue recovery report is not required unless the recovering transplant surgeon notes unusual pathology or

injury

____ Yes, GOH to arrange for organ recovery operative reports from each recovering surgeons

GOH will arrange for a formal, typewritten report describing the bone/tissue recovery will be forwarded to the Coroner's office in a timely fashion. This report is intended to be filed in the permanent file of the deceased. The operative report will be signed by the recovery staff and include the following information:

- Identification of the donor with hospital/medical record number
- Date, time, and name of physician pronouncing death.
- Brief clinical history and evaluation as a suitable donor.
- Pre-operative condition of the area of the body that is involved in or impacted by the recovery.
- Names of all staff involved in the recovery.
- Description of any preexisting injuries within the site of dissection.
- Description of each bone/tissue recovered as normal, or specify any abnormalities.
- General statement of the operative procedure and the condition of the body after the organ recovery is completed.

Corneal T	Tissue Operative Report	
No, a d	a corneal tissue operative report is not required unless the recoverin	g transplant surgeon notes unusual
pathol	ology or injury	
Yes, G	GOH to arrange for organ recovery operative reports from each reco	overing surgeons
`	GOH will arrange for a formal , typewritten original of the recovery of eye r	
	Coroner's office in a timely fashion. This report is intended to be filed in the	-
	operative report will be signed by the recovery staff and include the followi	•
05	 Identification of the donor 	
	 Date and time of the recovery. 	
	-	
	 Name(s) of the recovery staff. 	e ware callested
	 Type of eye tissue recovered, whether vitreous and/or blood sample 	
11 Deet	 A general statement of abnormalities or noteworthy conditions exist 	ing prior to recovery.
	-Transplant Follow-up Information	
	onceivable that the health of a donated organ may be called into question during su	
	organ function was tested by transplant personnel prior to organ recovery. If this sl ner's office forensic pathologist to advise as to the outcome of the transplant surger	
	ient survived. There would be no necessity to know the identity of the recipient(s)	-
12. Testin	imony	
	request, the Gift of Hope Representative will prepare a report providing the name	c and contact information for each of the
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individu		
	duals who participated in the organ and/or tissue recovery. All individuals who participated in the organ and/or tissue recovery.	
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