Issue Involves: OPO 34505N
Issue Reported by: UNOS Member Quality Patient Safety Coordinator

Issue: OPO 34505N received an autopsy report specifying a donor had right testicular embryonal carcinoma. The Medical Director reviewed the report, per the usual OPO process, but overlooked this finding. The liver recipient center contacted OPO 34505N after the liver recipient showed a germ cell tumor, prominently embryonal in type. The other recipient from this donor, a heart transplant patient, had already died due to graft rejection and organ failure.

Relevant OPTN Policy:
15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions: "The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows...Malignancy or other findings highly suggestive of malignancy...To...1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal..."

Relevant Correspondence:
Inquiry to OPO 34505N - sent on February 28, 2019
Response from OPO 34505N - received on February 28, 2019
Notification letter to OPO 34505N - sent on March 7, 2019
Additional Response from OPO 34505N - received on March 12, 2019

Donor Analysis:
The donor was a 20-year-old male. The donor had an altercation with police who shocked him with a Taser three times, causing him to fall and hit his head. EMS administered Haldol and Versed and the donor walked himself to the ambulance, where he went into asystole. Cause of death was "complications of excited delirium associated with probable drug abuse." The donor was PHS Increased Risk due to recent incarceration and receiving hemodialysis during donor management, but had no known history of cancer.

Member Response:

OPO 34505N reported:

- **February 18, 2018**: Organ procurement was completed. A physical assessment noted "scrotal swelling."
- **February 19, 2018**: A Medical Examiner (ME) performed an autopsy on the donor.
- **March, 2018**: OPO 34505N reached out to the ME's office to inform them that the OPO was waiting for final autopsy results. The ME informed OPO 34505N that the final report was not finalized, as it was awaiting pending toxicology results.
- **June 11, 2018**: The final autopsy report was received by OPO 34505N. The OPO Medical Director (MD) reviewed, dated, and initialed the report, but overlooked the finding regarding the malignancy
- **February 15, 2019**: The liver recipient center called OPO 34505N to inform them that a large mass was found on the recipient's liver during the one-year follow-up appointment. Biopsy indicated the mass was a germ cell tumor, possibly embryonal. The liver center asked OPO 34505N to review their medical record to determine risk for the tumor being donor derived.

- **February 15, 2019**: OPO 34505N re-reviewed the autopsy report and found the reference to the malignancy. They reported the finding to both receiving centers and to UNOS the same day.
- OPO 34505N had a practice of requesting donor autopsy reports, but this was not a written requirement in OPO policy.
- Autopsy reporters were not part of "formal chart closure" – OPO 34505N would close a donor record even if autopsy findings were pending.

OPO 34505N corrective actions:

- When autopsy reports are received, the OPO Information Associate or secretary will add the donor ID and scan the report into the OPO's EMR, resulting in an immediate email to the MD and Executive Director (ED) prompting review of the autopsy.
- The MD and ED, or their designees, will both review every preliminary and final autopsy within 24 hours of receipt, and date and initial each page.
- On weekends and holidays, when no staff are in the office, on-call staff will monitor a common electronic inbox. The person on-call will review any incoming reports and make any required notifications to UNOS or transplant centers within 24 hours. The following business day, the report will be reviewed by the MD or ED for final sign off.
- A checkbox indicating the autopsy report has been received and reviewed will be added to the EMR.
- The Donor QA Committee will audit compliance with these new processes.
- All MEs in the OPO 34505N DSA will receive education from the OPO about possible donor-to-recipient disease transmissions and the importance of communicating early findings to the OPO. Education will re-occur annually, or within one month of a newly appointed ME.
- OPO 34505N sent correspondence to all MEs in their DSA to inform them of the general details of this case and ask for their help in early identification of donor conditions that could possibly be transmitted to recipients. OPO 34505N will contact the chair of the State ME's board to request time on the agenda at their next statewide conference.
- Within one to three days of procurement, OPO 34505N will fax a form to the ME asking if the preliminary autopsy findings show risk for possible donor-to-recipient disease transmission. If the form is sent back with a box checked "Yes," OPO staff will contact the ME within 24 hours. OPO 34505N's EMR will be programmed to automatically re-send this fax every week until the ME returns the form.
- OPO 34505N will contact other OPOs to ascertain how they deal with ME follow-up.
- If the donor does not become a ME case, OPO staff will ask the donor family if they are having a private autopsy performed and ensure that report is received.
- All changes to the OPO's practice of requesting, reviewing, and reporting on autopsies will be reflected in updated policy changes.
- Staff will be notified of all changes to policy and practice.
- As part of the corrective action plan, other test results reviewed solely by the MD were identified and will now be reviewed by two parties.
- As part of the corrective action plan, policies related to reporting of donor culture result were amended to ensure that results are reported to UNOS and receiving centers within 24 hours.

Redacted - Privilege/Privacy

From: [redacted]
Sent: Tuesday, February 19, 2019 2:38 PM
To: Patient Safety System Email Group
Cc: Redacted - Privilege/Privacy
Subject: REFERRAL TO SAFETY ANALYST - [redacted] Malignancy not reported to TXCs and OPTN

PDTE 104109 came in on through the Safety Portal on 2/15/19 for a confirmed germ cell tumor, predominantly embryonal in type in the liver recipient ([redacted] of [redacted]

[redacted] is the donor OPO, contact is [redacted] I reached out to her yesterday after the LI TXC ([redacted] reached out, and spoke with Redacted - Privilege/Privacy, concerned that the OPO did not report malignancy findings from the donor autopsy. The autopsy findings were also referenced by the OPO in the PDTR stating, "Right testicular embryonal carcinoma found on autopsy of the donor." Yesterday, OPO asked if she could return my call today. She called back today and apologized for the delay and stated that she wanted to make sure she was communicating the correct information to me. She said that the autopsy was received in June 2018, transplants were 2/18/2018 (Heart and Liver for this donor). The autopsy went to their Medical Director and the right testicular embryonal carcinoma was missed on his review. It was not detected by the OPO until [redacted] did further review of the donor's documentation after being contacted by the LI TXC regarding the recent event submitted.

Please let me know if you need any additional information from me.

[redacted]
Patient Safety Coordinator

UNOS UNITED NETWORK FOR ORGAN SHARING

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[redacted]

www.unos.org

SECURE UNOS
CONFIDENTIAL MEDICAL PEER REVIEW CONTENT/CONFIDENTIALITY STATEMENT

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[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

February 28, 2019

VIA SECURE EMAIL

[redacted]

Dear [redacted]:

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the matter suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the matter is assessed as both time-sensitive and serious, this department will alert OPTN leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN/UNOS bylaws or policies associated with the matter. Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing the reporting of carcinoma in donor [redacted]. Our preliminary analysis indicates that [redacted] received an autopsy report in June of 2018, which showed the donor had right testicular embryonal carcinoma. This information was not reported to UNOS or to the receiving transplant centers.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or

[redacted]

bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by OPTN leadership, including the Membership and Professional Standards Committee (MPSC), and in some cases the OPTN Board of Directors.

Please address the following issues related to the reporting of carcinoma in this donor:

- Explain why the autopsy findings were not reported to UNOS and to the receiving centers upon receipt. Provide a root cause analysis, if available.

- What quality assurance measures are in place to ensure that post-procurement donor test results are reported to UNOS and to receiving centers in a timely manner? Include a copy of your policies and/or Standard Operating Procedures regarding reporting of post-procurement donor test results.

- What corrective actions have been implemented or are planned to prevent recurrence of this type of oversight? Include any documentation that supports these corrective actions, such as revised policy, staff re-training materials, etc.

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for monitoring compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by **March 14, 2019**. Responses can be sent via mail, email and/or fax. I can be contacted at [redacted] Thank you in advance for providing the additional information requested.

Sincerely,

[redacted]
Safety Analyst
UNOS Member Quality

cc: [redacted] OPTN/UNOS Alternate Representative
[redacted] Director, UNOS Member Quality

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: [redacted] response
Date: Thursday, February 28, 2019 1:59:48 PM
Attachments: AFBP150 cover letter.pdf
1. RCA_CAP [redacted].doc
3. [redacted] 209 Medical Examiner Policy CY19newDRAFT.doc
4. [redacted] 117 Training Policy CY19_new DRAFT.doc
2. [redacted] 801 QA Policy CY19newDRAFT.doc
5. ME Letters.pdf
6. March 2019 Clinical Quality meeting agenda.docx
7. Prelim Autopsy request.docx
8. [redacted] 220 Post Procurement Follow Up and Reporting CY19FINAL.doc

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Good afternoon [redacted]

This email and the attachments are in response to your inquiry letter we received today. This became an urgent matter beginning on February 15, 2019. Since then, we have been actively working through the items on the corrective action plan we developed following our root cause analysis (RCA). We are also in regular communication with the [redacted], and hope and pray their patient recovers.

Attached is our cover letter to you, our RCA and CAP, three amended [redacted] policies, letters we sent to our Medical Examiners, an upcoming staff training agenda, a newly created form called a Preliminary Autopsy Request, and our standing (unchanged) Post Procurement Follow up and Reporting policy.

Please let us know if you need anything further, and as I outlined in our cover letter to you, we will forward any additional changes that we may make.

[redacted]

February 28, 2019

Safety Analyst
UNOS Member Quality

Dear

This letter is in response to your recent inquiry regarding donor from 2/18/18 with a cross-clamp time of 1344. This donor was an accidental death and therefore had an autopsy by the local Medical Examiner. The autopsy report was provided to OPO 4 months following the death of the donor and subsequent heart and liver transplantation.

At , when the medical director receives an autopsy report, he/she reviews it, and only contacts the director of clinical operations to report any findings that may indicate a communicable disease transmission. The director of clinical operations would then contact the patient safety contacts at each transplant center, the tissue and eye banks, and would follow the OPTN/UNOS DTAC protocol. If the medical director does not observe any questionable findings, then he/she dates and initials the report and gives it to the information associate or a secretary to upload into , the web-based donor database.

On Friday morning, February 15, 2019, OPO received a call from a liver center transplant coordinator who stated that during the liver transplant recipient's one-year follow-up appointment, an ultrasound revealed a large liver mass. Biopsy of the mass indicated it was a germ cell tumor, possibly embryonal. The coordinator asked if we would review our donor record to determine if this could have been donor derived. Upon review of the donor record, the medical examiner's autopsy report was reviewed and it clearly stated the donor had testicular cancer. The medical director overlooked this critical finding when he originally viewed the Medical Examiner's autopsy report on June 11, 2018. This is the reason why the autopsy findings were not communicated to TXC nor UNOS/DTAC.

This became a priority issue for , as we take potential or actual disease transmission very seriously. The next business day, February 18, 2019, the medical director, the executive director, the entire management team and quality improvement committee performed a root cause analysis and developed a corrective action plan, which are enclosed for your review. The root cause analysis led to policy/practice changes (attached), the need for medical examiner education—which began with a letter to all of our medical examiners (attached), staff education regarding this event and the new policies (agenda attached), and the creation of a new form called Preliminary Autopsy Request form (attached). No changes were made to our Post-Procurement Follow Up and Reporting policy because had the potential disease transmission been discovered, it would have properly been reported. It is attached for reference.

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Please let me know if you need anything further. If we learn anything else or if we change any additional practices, we will forward that information to you. Finally, if there is someone reviewing this who may have suggestions, we would like to hear them.

Sincerely,

[redacted]

Executive Director

[redacted]

cc: [redacted]

Root Cause Analysis & Action Plan – Donor Derived Cancer Transmission

Date of RCA: 2/18/19
Reference #: [redacted] **Facility:** [redacted] **Category:** Major / Sentinel Event **Team:** [redacted]

Patient History & Initial Assessment

This patient was a [redacted] brain dead organ donor at [redacted] after sustaining head injuries and a cardiac arrest following a confrontation with police officers over public, disruptive behavior classified as excited delirium. Past medical / social history obtained by the father and included mental disorders that required at least one hospitalization in a psychiatric facility, medical marijuana use, short periods of jail time due to theft, DUI, and violation of probation.

Date/Time/ Reference	Details of the Event / Timeline
2.9.18 2345 [redacted]	Patient admitted to [redacted]
2.15.18 2000 [redacted]	Referral of this patient made to [redacted] (OPO).
2.16.18 1828 [redacted]	Brain death declared.
2.16.18 1828 [redacted]	Informed the family of patient's registered decision to donate, for which they supported. The past medical and social history was obtained at this time from the father of the donor, who indicated no cancer history in the donor.
2.16.18 2040 [redacted]	[redacted] contacted the Medical Examiner (ME) who cleared the patient for organ donation, but did not permit tissue donation due to the multiple Taser markings the ME wanted to preserve.
2.16.18 2300 [redacted]	A physical assessment was done by OPC #1.
2.17.18 0930 [redacted]	A bronchoscopy was completed, unremarkable.
2.17.18 1130 [redacted]	A physical assessment was done by OPC #2 with documentation of "redness/irritation noted between the legs/scrotal area with scrotum having notable swelling".

2.17.18 1340 [redacted]	A chest, abdomen and pelvis CT was performed. "The liver, spleen, kidneys, adrenals, pancreas and gallbladder were unremarkable. Small amount of ascites, no pelvic masses or lymphadenopathy".
2.18.18 0900 [redacted]	A physical assessment was done by OPC #3 with a drawing that included scrotal swelling.
2.18.18 1230 [redacted]	The donor was taken to the OR for liver and heart recovery for transplant, and small intestine recovery for research. Organ recovery was unremarkable, and cross-clamp was at 1344 [redacted] Abdominal surgeon attestation that there were no contraindications for donation, [redacted] surgeon signature. Following organ recovery, the body was transported to the morgue to await pick up by the [redacted] Medical Examiner's office.
2.19.18 0918 [redacted]	The pathologist in the [redacted] Medical Examiner's office performed the autopsy on 2/19/18 at 0918 [redacted] According to the autopsy report, during the autopsy, "numerous hemorrhagic nodules were noted on the right testicle." Pathology later revealed right testicular embryonal carcinoma, and this was included in the final autopsy report. Also included, was a statement in all capital letters: "EVIDENCE OF MEDICAL INTERVENTION AND ORGAN PROCUREMENT". There were several other statements regarding organ recovery throughout the report.
March 2018	The [redacted] Information Associate reached out to the ME office by e-fax to inform them we were still waiting on the final autopsy report. A quick response from the ME office indicated the final report was not available, as they were still waiting on toxicology results.
6.11.18	[redacted] received the final autopsy report by U.S. Mail. The [redacted] secretary wrote the UNOS ID on the report and gave it to the Medical Director for review.
6.11.18	The [redacted] Medical Director reviewed the autopsy report, dated, initialed, and submitted it to the QA staff for scanning into the donor record. No information about the donor having testicular cancer was noted by the Medical Director.
2.15.19 0900	On the morning of February 15, **2019**, the Director of Clinical Operations received a call from a liver txc transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI. Biopsy of the mass indicated that it was a germ cell tumor probably embryonal. It was asked by the [redacted] coordinator if we would review our donor record to determine if this could have been donor derived.
2.15.19 0930	The Director of Clinical Operations quickly began reading through the donor record and eventually found the autopsy report from the ME office that revealed testicular embryonal carcinoma. She immediately notified the Associate Executive Director who then notified the Executive Director.

2.15.19 1000-1300	Between the hours of 1000-1300 [redacted] (liver), [redacted] (heart) and DTAC were notified of the finding. During the call to [redacted] the transplant coordinator stated that the heart patient died of multi-system organ failure in November of 2018, and never demonstrated any evidence of cancer. The [redacted] liver surgeon indicated that treatment would begin for the recipient and that they reported this possible disease transmission to DTAC.
2.15.19 1605 [redacted]	The Executive Director called the Medical Director to inform him.

Questions	Details of the Event
What are the current steps in the process, as designed?	Current practice is: Medical Examiner may or may not send an autopsy report without prompting. No written requirement through policy for [redacted] to contact the Medical Examiner's office for a final autopsy report, though this has been the practice for the [redacted] Information Associate. In the medical examiner section in [redacted] web-based database, it asks whether an autopsy was done. This has a yes or no box to check (it was checked yes for this case). The autopsy report is not part of formal chart closure, i.e., a donor record can close even if an autopsy is pending. When an autopsy report is sent to [redacted] the secretary or Information Associate receives the report and sends it to the Medical Director for review. The Medical Director reviews the autopsy report for anything that could lead to a disease transmission in a transplant recipient. If there is no evidence for possible disease transmission, the Medical Director initials, dates the front page of the report, and then gives it back to clerical staff for scanning into the donor record. If there is evidence for possible disease transmission, the Medical Director notifies the Director of Clinical Operations or his/her designee. The Director of Clinical Operations or his/her designee is responsible for notifying the AED, ED, patient safety contacts at all transplant centers, tissue, and eye banks affected, and filling out the requirements of the OPTN/UNOS DTAC.
What other programs were possibly impacted as a result of this event?	[redacted] Liver Transplant [redacted] Heart Transplant OPTN/UNOS DTAC

Questions	Analysis of the Event (cancer transmission) Why Did it Happen?	In Our Control Yes/No	Root Cause?	Contributing Cause? Can only be "yes" if not a root cause
What steps were involved that possibly contributed to the event?	Lack of communication from ME to OPO upon findings of testicular masses and identification of cancer	No	Yes	No
	ME report arrived 4 months after the donation and subsequent transplantation	No	Yes	No
	Lack of written protocol for reviewing/receiving of ME reports	Yes	No	possible
	Medical Director overlooked cancer in report	Yes	Yes	No
	Single person review of document	Yes	Yes	No
	Lack of tracking outstanding autopsy reports	Yes	No	Yes
	Initialing only first page of autopsy report by medical director	Yes	No	possible
	Lack of education for MEs to make aware that cancer can be transmitted from donor to recipient, and that the OPO should be notified	Yes	Yes	No
Human Factors: What human factors were relevant to the outcome?	Single review of autopsy report	Yes	Yes	No
	ME education	Yes	Yes	No
Policies & Protocols: What impact did the policies related to this event have on the outcome?	Lack of a specific process outlined in policy for autopsy receipt and review	Yes	No	Yes
	Lack of a protocol for educating Medical Examiners	Yes	No	Yes

Questions	Analysis of the Event (cancer transmission) Why Did it Happen?	In Our Control Yes/No	Root Cause?	Contributing Cause?
Written documentation: To what degree was all necessary information available when needed? Accurate? Complete?	ME report sent to the OPO four months after the autopsy	No	Yes	No
	Medical Director practice of initialing only the first page of the autopsy report	Yes	No	Possible
	Method of receiving some autopsy reports in the mail	No	No	Possible
Oral Communication: To what degree was oral communication among participants inadequate?	Lack of communication from ME to OPO when testicular cancer was confirmed.	No	Yes	No
	Lack of communication from OPO to ME to obtain final report	Yes	No	Yes
Written/Oral Communication: What are the barriers to communication of potential risk factors?	Education of MEs	Yes	Yes	No
	Availability of autopsy reports to OPO	No	No	Yes
Staff Competency: What training systems are in place to assure adequate training/competency levels as related to this event?	ME competency with potential disease transmission and communication to the OPO	Yes	Yes	No
Staff Performance: To what degree is staff performance addressed?	Physical exam training begins during orientation and is ongoing as evidenced in our training records. [redacted] physical exam training is comparable to OPOs and tissue banks throughout the industry.	Yes	No	No
	Medical Director is trained and qualified to review autopsy reports	Yes	No	No

CORRECTIVE ACTION PLAN (CAP)

	Risk Reduction Strategies	Date Implemented	Quality Monitoring	Responsible Personnel	Completed
Action Item #1	Two clinical reviews of autopsy report. The Medical and Executive Directors, or their designees if unavailable, will review every Medical Examiner autopsy initial and final reports (and private autopsy when available) within two business days from receipt of the report. Each page of the autopsy report will be dated and initialed by both parties. Practice changes will be reflected in amendments to the Donor Record Quality Assurance Policy ([redacted] 801), the Medical Examiner policy ([redacted] 209), and a checkbox will be added to [redacted] All staff will be notified of the change and given ample opportunity to ask questions.	2/15/19 2/28/19	The donor record QA committee will assure that both the Medical Director and the Executive Director (or their designees) have both dated and initialed each page of the initial and final autopsy report, that the report was scanned into the donor record, and that the newly formed check box was completed in [redacted]	[redacted] QA committee [redacted]	✓ ✓
Action Item #2:	Amend [redacted] policy and procedure regarding receiving autopsy reports: Implement a backup system with secretary and information associate receiving autopsy reports and the process for handling them. Autopsy tracking system will be developed in [redacted] A new checkbox will be added into [redacted] for private autopsies as well. When the report is received, the information associate or secretary will add the UNOS ID, date and initial, write the number of pages received, and scan into [redacted] Programming changes in [redacted] will result in an instant and automatic email to the medical and executive directors that there is an autopsy report to review. Practice changes will be reflected in amendments to the Donor Record Quality Assurance Policy ([redacted] 801) and the Medical Examiner policy ([redacted] 209). All staff will be notified of the change and given ample opportunity to ask questions.	2.26.19 3.15.19 2.28.19	Donor record QA committee will track receipt, review and upload of final autopsy report from the Medical Examiner into the donor record.	[redacted] [redacted] or [redacted] for [redacted] programming changes. [redacted]	✓ Pending ✓
Action Item #3	All Medical Examiners in the [redacted] DSA will receive education from [redacted] regarding possible disease transmission from donor to recipient, and the importance of communication to the OPO of early findings, and again on the final report. This education will	2/27/19	The CQI committee will be responsible for assuring documentation of newly required training by adding	[redacted]	✓

	occur within days of this RCA, then annually or within one month of a newly appointed ME.		this to the CQI agenda once per year as an audit of training activities for Medical Examiners.		
	Specific, focused contact with ME from [redacted].	2/28/19		[redacted]	✓
	This practice change will be reflected in the Training policy ([redacted] 117). All staff will be notified of the change and given ample opportunity to ask questions.	2/28/19	Staff education and training records	[redacted]	✓
Action Item #4	Create a form that is faxed to the Medical Examiner's office within 1-3 business days that includes: 1. Upon initial autopsy, were there findings that could include possible disease transmission from organ donor to recipient: Y ☐ N ☐ 2. Please fax back to [redacted] at [redacted] 3. If the Yes box is checked, a representative from [redacted] will contact your office within one business day of receipt.	2/26/19 3/15/19	The donor record QA committee will assure the fax was submitted to the ME office as evidenced by the log-in history in [redacted] [redacted] will be programmed so that the form is sent automatically to the ME every week until it is received back.	[redacted]	✓ Pending
	This practice change will be reflected in [redacted] the Donor Record Quality Assurance policy ([redacted] 801) and the Medical Examiner policy ([redacted] 209). All staff will be notified of the change and given ample opportunity to ask questions.	2/28/19	Training for this will be for all clinical staff and all new clinical staff from this date forward.	[redacted]	✓
Action Item #5:	Contact the Chairperson of the state [redacted] Medical Examiner [redacted] and ask to get on the agenda for the next statewide meeting regarding potential disease transmission and the importance of communicating early and often with the OPO.	First contact by 2.26.19	Medical Examiner [redacted] agenda	[redacted]	✓
	Confirmation that [redacted] will present at next MEC meeting.	4/15/19	Medical Examiner [redacted] agenda	[redacted]	Pending
	Contact other OPOs about Medical Examiner follow up with preliminary and/or final autopsy reporting to ascertain if there is something with their processes that could help improve ours.	3/15/19	Report at the Director's meeting	[redacted]	Pending

PRIVILEGED DOCUMENT: [redacted]

[redacted]

POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

SUBJECT: Donor Record Quality Assurance Policy

PURPOSE: To provide guidelines regarding quality assurance as it pertains to donor record completion and to provide guidelines regarding the secure retention of all [redacted] donor files.

POLICY STATEMENT: Clinical coordinator of record is responsible for completion of all required documentation as outlined on the Donor Record Quality Assurance Checklist (in [redacted] The Record Quality Assurance Committee will meet weekly to ensure compliance with this policy. Director of Clinical Operations and the Medical Director will sign off on all completed records after the Record QA Committee has determined that the record meets document requirements. All donor records—including consented-not-recovered (CNR) cases—will be maintained in a locked electronic format within [redacted] These files will be maintained for a minimum of 10 years.

CONTENTS:

1. Completion of donor records

   a. The primary clinical coordinator of record shall be responsible for completion of all documentation data entry within the time frame outlined. All corrections or additions to initial paper documentation must be made with a single line through the altered text, initialed and dated by the individual making the correction.
   b. All initial paper documentation scanned and contained within the donor records shall be completed using ink.
   c. All initial donor paperwork items must be completed (a strike-through line of "N/A" is an acceptable entry). Any additional information that is needed to be entered after the strike thru is made will require a note in [redacted] of justification. Any fields that are blank in [redacted] after validation occurs are to be considered as intentionally left blank. Once the electronic record is validated, it is locked for changes requiring the donor record to be opened at the direction of the data quality analyst or [redacted] administration.
   d. All paper documentation will be included in the donor files as scanned electronic files in [redacted] This will include documents related to: declaration of death, consent/authorization, medical-social history, ABO, serologies, diagnostic testing, OR documentation and recipient information. When no longer needed all paper documents (after scanning into [redacted] will be deposited into the secure documentation shred receptacle.
   e. Only those [redacted] employees with a need to know shall access the contents of the donor records for purpose of modification.
   f. When access to a donor record is needed for modifications after the record has completed the QA process a staff member will need to get approval from the data quality analyst or a member of [redacted] administration
   g. With the exception of OPOs or transplant centers, when copies of a donor record are requested by non-[redacted] entities, [redacted] will always consult Legal Services before processing any request for copies of any donor record. Copies may be provided to donor/transplant entities involved with that donor.

[redacted]

POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

h. The Medical Director and the Executive Director (or his/her designees) are responsible for reviewing the initial and final autopsy reports from the Medical Examiner or in the rare instance of a private autopsy within two business days of receipt. This will be evidenced by the reviewers' initialing and dating of each page of the final autopsy report, and by documenting the review in [redacted]. Any findings by the Medical Director or the Executive Director of potential communicable diseases will be reported to the Director of Clinical Operations, or his/her designee, in order to initiate the responsibilities of DTAC and contacting the transplant programs, tissue and eye banks.

2. Record Quality Assurance Committee

a. The Record QA Committee shall be comprised of the director of clinical operations, data quality analyst, information associate, secretary, and a clinical coordinator who will attend as workload permits. Other staff may be directed to participate as well.
b. The Record QA committee will meet once a week to review donor files and ensure compliance with document deadlines outlined in [redacted] under record tracking.
c. Coordinators must participate in the weekly meeting, either in person or via conference call to discuss and plan timely submission of documents and completion of electronic data entry.
d. Records with outstanding documentation will remain within the committee's weekly review, with a target date of completion set.
e. The assistant executive director, director of clinical operations or associate director of clinical operations will complete the DDR data upload and validation to UNET within the 28 day deadline imposed by UNOS.
f. The clinical coordinator or a member of the QA committee will fax to the Medical Examiner's office within 1-3 business days, the Preliminary Autopsy Request form, found on [redacted]
g. If the Medical Examiner's office returns the form with the checkbox marked yes, the medical director or his/her designee will contact the medical examiner's office within one business day of receipt of that information to obtain the potential communicable disease transmission information.
h. The medical director will notify the AED, ED, and then the director of clinical operations at [redacted] of the potential disease transmission from organ donor to recipient(s) so that he/she or his/her designee can begin the DTAC process and notify all potentially affected transplant programs, including tissue and eye banks.
~~e.~~ i. The secretary and the information associate will be cross-trained to receive initial and final autopsy reports from the Medical Examiner's offices. This back-up system will assure all autopsy reports are received and passed to the medical and executive directors in a timely manner.
j. The Record QA committee will be responsible for assuring that both the medical director and executive directors (or his/her designees) have reviewed, dated, and initialed each page of the final autopsy report before it is scanned into [redacted]. The autopsy tracking system within [redacted] will be updated.

Note: Most medical examiner reports received are final. Initial reports are very infrequent.

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POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

3. Final Approval

   a. When a record is completed and approved by the members of the Record QA Committee, it will be directed to [redacted] administration for final sign off.
   b. Administration required for final sign-off includes the medical director and the director of clinical operations. The target goal for final approval is the chart is closed within 90 days of recovery.
   c. If deficiencies are discovered, the electronic chart will remain open in the QA circulation for weekly review and correction of discrepancies.

[redacted]

POLICY NUMBER: 209
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

SUBJECT: Medical examiner cases

PURPOSE: To provide guidelines concerning organ donors under the jurisdiction of the medical examiner.

POLICY: It is the policy of [redacted] to obtain permission from the medical examiner prior to the removal of organs and tissues, in compliance with [redacted] Statute. Furthermore, it is the policy of [redacted] to develop a close working relationship based on mutual trust and collaboration to promote the release of medical examiner cases for donation. [redacted] Statutes can be found online.

CONTENTS:

1. **Obtaining Clearance for Donation from the Medical Examiner's Office:**
The clinical coordinator is responsible for requesting permission from the medical examiner for pre-autopsy removal of specific organs and tissues from a potential donor. Clearance for tissue donation will also be requested. The initial request is made to the medical examiner **in the county or district of jurisdiction, where the death occurred.** The clinical coordinator will provide the medical examiner's office with the following information:

   a. Name/age/sex/race/cause or circumstances of death
   b. Name and address of next-of-kin if requested
   c. Synopsis of injuries including CT scan reports, x-ray reports, other diagnostic imaging reports, reports of surgical procedures if requested
   d. Time of brain death declaration/intent for DCD recovery
   e. Location of incident and law enforcement agencies involved
   f. Any further information requested by the medical examiner's office

   Note: The clinical coordinator will document in [redacted] the name of the person giving clearance for donation, the date and the time. Restrictions, if any, will be documented in the space marked "restrictions." If no restrictions are given, the clinical coordinator will document "no restrictions." The clinical coordinator is responsible for assuring that visiting surgeons comply explicitly with any limitations set forth by the medical examiner regarding this procedure.

2. **Required Blood and Body Fluid Samples:**
On all medical examiner's cases, the clinical coordinator will provide the medical examiner with (at minimum) **2 red top blood tubes, 2 gray top blood tubes, and 1 purple top blood tube**. At the request of the medical examiner's office, the **clinical coordinator will provide one or all of the following samples:**
   a. **Pre-transfusion blood sample**
   b. **urine sample**
   c. **bile sample**

   All samples will be labeled with **donor name, date and time of sample drawn, draw location, UNOS ID, type of sample, and initials.** All specimens will be placed in a sealed bag for transport to the ME's office.

3. **Required Documentation:**
The clinical coordinator will provide the medical examiner's office with the following documentation:
   - Copy of the [redacted] donor information including consent and the medical/social history questionnaire.
   - Hospital record documentation including history and physical, progress notes, diagnostic imaging reports, consult reports, operative reports, consults from cardiology, pulmonary, cath lab for evaluation of heart and lungs for transplant, organ procurement specific operative notes and organ biopsy reports.

[redacted]

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- The clinical coordinator, information associate, or secretary will fax to the Medical Examiner's office within 1-3 business days, the Preliminary Autopsy Request form, found on [redacted]. The system [redacted] is programmed to resend the fax every week until a response is obtained from the Medical Examiner's office.

- If the medical examiner's office returns the form with the checkbox marked yes, the information associate or secretary will notify the medical director or his/her designee who will contact the medical examiner's office within one business day of receipt of that information to obtain the potential communicable disease transmission information.

- The medical director will notify the director of clinical operations at [redacted] of the potential disease transmission from organ donor to recipient(s) so that he/she or his/her designee can begin the DTAC process and notify all potentially affected transplant programs, including tissue and eye banks.

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4. **Photographs:**
In all medical examiner cases, the clinical coordinator will provide the ME with photographs of the donor pre-procurement for the purpose of documenting physical condition of the body prior to surgery. The following views are required for all medical examiner's cases:
   a. close-up of the head from above
   b. 1/3 view of the head and thorax from above
   c. 1/3 view of the abdomen and pelvis from above
   d. 1/3 view of lower extremities from above
   e. full head to toe from lateral view
   f. close ups of all injury sites
   g. close-ups of all tattoos, scars other identifying features

   Photographs for the medical examiner will have a card with the UNOS ID and date visible within the photo and all will be stored in electronic format. This information will be provided to the medical examiner's office. Copies of medical examiner pictures will NOT be maintained in [redacted] files or equipment.

5. **Abnormal Findings:**
The medical examiner needs to be informed of any abnormal findings discovered during the procurement surgery. The clinical coordinator will first contact the AOC to review abnormal findings and instruction regarding notification to ME will occur. These findings may be provided to the medical examiner by providing appropriate documentation or contacting the ME office during the procurement surgery.
   a. Abnormal findings will be documented on a hospital progress note or the organ procurement operative note.
   b. Document in detail the specifics of the abnormal finding i.e., organ damage, capsular tears, lacerations, hematomas and retroperitoneal injuries.
   c. Organ damage that does not preclude recovery is evaluated on a case-by-case basis. The administrator on-call MUST be consulted under this circumstance. This circumstance may require a call to the ME from the operating room to report the finding or taking a photograph of the organ and providing it to the ME via standard procedure.

6. **Chain of Evidence Procedures:**
All documentation and donor samples will be provided to the ME in a secure manner that maintains chain of evidence. All documentation, photographs and donor samples will be placed into the tamper-proof medical examiner's envelope. Once all information is enclosed, the envelope is sealed and cannot be re-opened. The

[redacted]

label for the ME envelope is filled out and placed on the front side of the envelope. The completed medical examiner's packet must remain with the body or be hand carried to the ME's office by the clinical coordinator.

7. **Medical Examiner Denial:**
The clinical coordinator will contact the AOC if the medical examiner declines the case for organ donation. The AOC will consult with [redacted] executive leadership to consider further action, including:
   a. Direct call from management to the medical examiner office
   b. Involvement of the [redacted] Medical Examiner [redacted]
   c. Direct call to the chief of the medical examiner of the involved district.

The medical examiner has final decision on clearance for donation. [redacted] is obligated to report all denials to the [redacted] Medical Examiner [redacted]

8. Medical Examiner Autopsy Reports

The information associate and/or the secretary at [redacted] will receive all medical examiner's reports by email or US mail. These reports may be the initial or final reports. Once received, the information associate or secretary will add the UNOS ID, initial and date, mark the number of pages received, and upload into [redacted]. This upload will generate an instant and automatic email to the medical and executive directors that there is an autopsy report to review.

The medical and executive directors, or his/her designees, will review all autopsy reports (initial and final) within two business days of receipt of the autopsy report to [redacted]. Each page of autopsy report will be dated and initialed before given back to the information associate or the secretary for uploading into [redacted]. If information in either the initial or final autopsy report suggests there is a potential for disease transmission from the donor to any recipient, the Medical Director and/or the Executive Director will notify the Director of Clinical Operations or his/her designee, to initiate the DTAC protocol and communication to the transplant programs, tissue and eye banks.

[redacted]

POLICY NUMBER: 117
CATEGORY: ADMINISTRATIVE
REVIEW: FEBRUARY 2020

Subject: Employee Orientation and Training

Purpose: To establish guidelines for providing orientation and on-going training for [redacted] employees, contracted staff, and Medical Examiners.

Policy Statement: It is the policy of [redacted] to provide all new employees with a comprehensive orientation curriculum that covers job responsibilities, core behaviors, and information related to corporate compliance, QAPI, [redacted] policies and procedures, HIPAA, HIV/AIDS, OSHA, blood borne pathogens, environment of care, infection control, risk management, patient safety and fire safety, occupational health, hazardous materials, code of conduct and goals.

[redacted] also will provide ongoing training and [redacted] annual in-services for all employees.

All current [redacted] policies can be found on the [redacted] portal/policies and procedures.
All [redacted] training checklists referenced in this policy can be found on the V-drive/training

All [redacted] Employees

1. As outlined in [redacted] Safety Policy, upon hire, all [redacted] employees shall receive education and training through [redacted] as part of their initial orientation, before reporting to [redacted] for their initial assignment, and annually thereafter. Areas of training include environment of care, infection control, HIPAA, risk management and corporate compliance. The infection control section of the educational program has information on HIV/AIDS, OSHA Bloodborne Pathogens Standard and the Tuberculosis Control Plan (see [redacted] portal), corporate compliance as covered during initial orientation provided by [redacted].

2. Documentation of completion of [redacted] new employee orientation will be kept in the employee's personnel folder.

3. Training on [redacted] Electronic Information Management System (EIMS), EMR is provided to [redacted] employees and contract coordinators needing access to perform their job duties through face-to-face instruction as well as webinar training, as outlined in the [redacted] EIMS policy.

4. All [redacted] employees (non-internal transfers) will spend their first day at [redacted] for new employee orientation and the remainder of the week at [redacted] for continuation of their orientation under the direction of the immediate supervisor and executive assistant. In accordance with the staff orientation checklist, new employees will be oriented on:

[redacted]

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a. Mileage reimbursement, expenses and American Express protocols
b. PTO documentation
c. Procedure and policy manuals
d. Use of office equipment, such as cell phones, pagers and laptops
e. Computer access and email
f. QAPI

5. During the employee's first week at [redacted] he or she may also meet with:

- Executive director
- Assistant executive director
- Accounting personnel
- Director of donor program development
- Donor family services coordinator
- Main office administrative staff
- Medical director
- Data analyst
- Clinical operations leadership

6. Select [redacted] employees will be given 30- and 90-day, post-hire interviews by a member of the management team if the supervisor identifies the need. These interviews will assess how the employees are assimilating to their new jobs and how the actual job duties compare to how they were presented to them during their pre-employment interviews.

Individualized Staff Training

1. **Clinical Coordinators**
   a. Clinical coordinators will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of clinical operations. No clinical coordinator will be considered fully trained until all proficiencies have been verified as completed or met by the director of clinical operations.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the clinical coordinator training orientation skills check list, and kept in the employee's [redacted] personnel file.
   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, real time interaction with the administrators on call, internal and external peer input, and employee assessments during educational offerings.

[redacted]

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2. **Contract Organ Procurement Coordinators**
   a. Contract coordinators will be provided with or provide confirmation of, training that includes corporate compliance and blood borne pathogens.

3. **Family Advocates (FA)**
   a. FAs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the associate director of clinical operations/manager of family advocates. No FA will be considered fully trained until all proficiencies have been verified as completed or met by the associate director of clinical operations/manager of family advocates.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the FA checklist and kept in the employee's personnel file.
   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, real time interaction with the administrators on call, internal and external peer input, and employee assessments during educational offerings.

4. **Hospital Services Coordinators**
   a. HSCs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of donor program development (DPD). No HSC will be considered fully trained until all proficiencies have been verified as completed or met by the director of DPD.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the HSC training checklist and kept in the employee's personnel file. In accordance with the training checklist, HSCs will be oriented on:

      - Introduction to the HS process, i.e., timely donor referrals and assessments,
      - Data collection procedures
      - Marketing skills
      - Death record and variance review
      - Professional education presentation skills
      - Electronic documentation of hospital binders
      - [redacted] training

   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, internal peer feedback, external peer feedback, shadowing in the field, and deviation audits.

[redacted]

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5. **Public Education Coordinators**
   a. PECs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of donor program development (DPD). No PEC will be considered fully trained until all proficiencies have been verified as completed or met by the director DPD.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the PEC training checklist and kept in the employee's personnel file. In accordance with the training checklist, PEC will be oriented on:

      - Public speaking and presentation skills
      - Familiarity with donor family services
      - Familiarity with OPO operations

   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, internal and external peer input, and routine competency testing.

6. **Donor Family Service Coordinators**
   a. DFSCs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of DPD. No DFSC will be considered fully trained until all proficiencies have been verified as completed or met by the director of DPD.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the DFSC training checklist and kept in the employee's personnel file. In accordance with the training checklist, DFSCs will be oriented on:

      - Familiarity with OPO operations
      - Familiarity with donor database and donor chart protocols
      - Understanding of needs of donor families in time of grief

   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, internal and external peer input, and routine competency testing.

7. **Accounting Staff**
   a. Accounting staff will be trained in all areas of their job function for a period lasting approximately six months Training will be under the supervision of the executive director and other accounting staff.

[redacted]

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b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

8. **Data Management Staff**
   a. Data management staff will be trained in all areas of their job function for a period lasting approximately six months. Training will be under the supervision of the executive director and other data-related staff.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

9. **Clerical Staff**
   a. Clerical staff will be trained in all areas of their job function for a period lasting approximately six months. Training will be under the direction of their immediate supervisor and other clerical staff.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

Annual and Ongoing Training

1. All [redacted] employees will complete the following mandatory inservices on an annual basis:
   - Fire safety
   - Infection control
   - HIPAA
   - Corporate compliance
   - Patient safety
   - Any other inservices as needed and requested by [redacted] and/or [redacted]

2. The OPO executive director, medical director, senior management, procurement coordinators and advisory board members will review annually the [redacted] and [redacted] policies on conflict of interest.
3. Clinical operations department employees will complete annual core competency requirements. Specific core competencies will be dictated by position. Some skills where annual core competency is demonstrated include but are not limited to:

   - Authorization
   - Obtaining medical-social history
   - Donor management
   - Packaging
   - DCD assessment

4. Ongoing training will be offered to all employees.

[redacted]

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5. Ongoing training that offers continuing educational credits will be made available to all staff holding clinical licensure. Documentation of course completion will be kept in employee's personnel file. Supervisors will review individual training files annually when preparing for the employee's evaluation. [redacted] will allow time off for employees to attend CEU classes.

6. All Medical Examiners in the [redacted] DSA will receive education from [redacted] regarding possible disease transmission from donor to recipient, and the importance of communication to the OPO of early findings. This education will occur annually, and will be documented in [redacted] training records. The continuous quality improvement committee will be responsible for assuring the documentation of this training.

Administrator-On-Call Training

1. Individuals identified as potential AOCs will be trained in those responsibilities by one or more of the following:

   - Medical director
   - Director of clinical operations
   - Associate director of clinical operations

2. Once an individual is proficient and can assume independent AOC responsibilities, a letter of competency will be documented by the Medical Director and placed in the employee's file.

[redacted]

February 27, 2019

[redacted]

Dear Dr. [redacted]

We are writing about an important matter and asking for your immediate help. There have been organ donor cases across the U.S. that were also ME cases, and communicable disease transmissions occurred in the organ recipients that might have been able to be treated in a more timely manner had the OPO received the ME autopsy report sooner. In a most recent case, the ME found and confirmed testicular cancer, but the report did not arrive to the OPO for 5 months due to other tests that were unrelated to the testicular cancer but possibly related to the cause of death, that delayed the report. The recipient did end up with cancer in his new organ that doctors are sure originated from the donor. We understand that there are many factors that cause delays with the ME's ability to share the final autopsy reports.

Therefore, [redacted] has created an Initial Autopsy Findings form that we will be faxing Medical Examiner's offices throughout our service area within 1 to 3 business days of an organ donor case. We have made this such that it only requires a check to a yes or no box to a single question to you that asks: upon initial autopsy if there were things that could include possible disease transmission from an organ donor to a recipient. I have attached this form for you to review. Please contact us with any questions or concerns you may have this returning this form back to us.

Our Medical Examiners are widely known as supporters of organ donation and are recognized as a key contributor to life-saving transplants. We are asking if you could help us devise a communications pathway in the rare event you discover a relevant medical concern for those patients in the course of the autopsy phase of your efforts.

The recipients of donated organs are all treated with immunosuppressive drugs to prevent rejection so communicating any potential transmissible disease in a timely manner is essential. The sooner the transplant teams know what they may have to deal with, the better the clinical outcome will be for their patients. Medical Examiners play a key role in the process of transplantation and can play a vital role in the clinical success for the patients benefiting from their cooperation.

Sincerely,

[redacted]

Medical Director, [redacted]

[redacted]

Executive Director, [redacted]

DONATE LIFE

A Donate Life Organization

[redacted]

[redacted]

February 27, 2019

[redacted]

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DONATE LIFE
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[redacted]

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Medical Director [redacted]

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Executive Director, [redacted]

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A Donate Life Organization

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February 27, 2019

[redacted]

Dear Dr. [redacted]

We are writing about an important matter and asking for your immediate help. There have been organ donor cases across the U.S. that were also ME cases, and communicable disease transmissions occurred in the organ recipients that might have been able to be treated in a more timely manner had the OPO received the ME autopsy report sooner. In a most recent case, the ME found and confirmed testicular cancer, but the report did not arrive to the OPO for 5 months due to other tests that were unrelated to the testicular cancer but possibly related to the cause of death, that delayed the report. The recipient did end up with cancer in his new organ that doctors are sure originated from the donor. We understand that there are many factors that cause delays with the ME's ability to share the final autopsy reports.

Therefore, [redacted] has created an Initial Autopsy Findings form that we will be faxing Medical Examiner's offices throughout our service area within 1 to 3 business days of an organ donor case. We have made this such that it only requires a check to a yes or no box to a single question to you that asks: upon initial autopsy if there were things that could include possible disease transmission from an organ donor to a recipient. I have attached this form for you to review. Please contact us with any questions or concerns you may have this returning this form back to us.

Our Medical Examiners are widely known as supporters of organ donation and are recognized as a key contributor to life-saving transplants. We are asking if you could help us devise a communications pathway in the rare event you discover a relevant medical concern for those patients in the course of the autopsy phase of your efforts.

The recipients of donated organs are all treated with immunosuppressive drugs to prevent rejection so communicating any potential transmissible disease in a timely manner is essential. The sooner the transplant teams know what they may have to deal with, the better the clinical outcome will be for their patients. Medical Examiners play a key role in the process of transplantation and can play a vital role in the clinical success for the patients benefiting from their cooperation.

Sincerely,

[redacted]

Medical Director, [redacted]

[redacted]

Executive Director, [redacted]

DONATE LIFE

A Donate Life Organization

[redacted]

[redacted]

February 27, 2019

[redacted]

Dear Dr. [redacted],

We are writing about an important matter and asking for your immediate help. There have been organ donor cases across the U.S. that were also ME cases, and communicable disease transmissions occurred in the organ recipients that might have been able to be treated in a more timely manner had the OPO received the ME autopsy report sooner. In a most recent case, the ME found and confirmed testicular cancer, but the report did not arrive to the OPO for 5 months due to other tests that were unrelated to the testicular cancer but possibly related to the cause of death, that delayed the report. The recipient did end up with cancer in his new organ that doctors are sure originated from the donor. We understand that there are many factors that cause delays with the ME's ability to share the final autopsy reports.

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Sincerely,

[redacted]

Medical Director, [redacted]

[redacted]

Executive Director, [redacted]

DONATE LIFE
A Donate Life Organization

[redacted]

[redacted]

[redacted]

MEETING NAME	DATE/TIME
Clinical Quality meeting	March 7th

SHARED DESKTOP LINK: [redacted] with the password [redacted]

ATTENDEES:

AGENDA	
Opening Remarks	
QUALITY: Authorization case review Donate Life month activities: [redacted] to review Documentation for current inmate: [redacted] to review	[redacted]
AFBP150: *brief review but don't go into a lot of details now. Review following policy changes.* [redacted] **801:** *Review Initial Autopsy Findings form and when to send it.Two person autopsy review. Need to make sure that if a case isn't a ME case we are still asking the family if they are having a private autopsy and document that in* [redacted] [redacted] **117:** *updating physical exam training and will be rolling that out to all the offices very soon. ME education-* [redacted] *and* [redacted] *are setting dates with ME offices to educate* [redacted] **209:** *Initial Autopsy Findings form (goes with 801)*	[redacted]
PROCUREMENT: **Vessel ties**- *using long ties on major vessels and reminding surgeons: go over funeral home issue* **UA requirements**: *remind people to do it at OR set and UPLOAD* **Sputum gram stain**: *NEED to get one at the donor hospital PRIOR to making lung offer. Remind everyone this is minimum information for a lung offer and it has to be upload prior to hitting send on the offer!*	[redacted]

PD corrections: *if a correction is sent from PD and it has a document that needs to be corrected send that to* [redacted] *and she will put the correction thru to me.* **Label PDSA:** [redacted] *will present his practice and we will get these labels out to all offices*	
EMR updates: Access issues	[redacted]
Upcoming training/events: -OR skills training -Dr. [redacted] education- mandatory -Monthly education series Clinical Education Feb- cancelled for OR training March 21- [redacted] May 16th- [redacted] - tissue donation	
Staffing Updates	[redacted]
Question and Answer Session	All
Adjournment	

[today's date]

Dear [*Medical Examiner name*],

We are requesting preliminary information on [*donor full name*], Date of Birth [*DOB*], Date of Death [DOD], who was authorized to be an organ donor. Your office indicated to our organ procurement coordinator that an autopsy would be performed.

Upon initial autopsy, were there findings that could include possible disease transmission from organ donor to recipient?

Please check one: Yes ☐ No ☐

Please fax this page back to [redacted] at [redacted] as soon as possible.

If the Yes box is checked, a representative from [redacted] will contact your office within one business day of receipt.

We appreciate your assistance,

[redacted]

Ref:[*unos id*]

DONATE LIFE
A Donate Life Organization

[redacted]

[redacted]

POLICY NUMBER: 220
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

SUBJECT: Post-Procurement Follow Up and Reporting

POLICY: The organ donor look-back policy and procedure contains information about cultures drawn during the organ donor process, the reporting of culture results to transplant centers, and potential disease transmission malignancy reporting.

PURPOSE: To provide guidelines regarding the responsibilities of the clinical coordinator and [redacted] administration concerning post-procurement follow up and reporting.

CONTENTS:

Donor Culture Reporting

1. **Blood Cultures** will be sent pre-recovery on ALL organ donors by the clinical coordinator while the donor is still in the ICU.
2. **Urine Culture** will be sent pre-recovery on ALL donors with renal function by the clinical coordinator while the donor is still in the ICU, regardless of renal placement.
3. **Sputum Cultures** will be sent on ALL donors where lungs are evaluated and specimens obtained.
4. **Preservation solutions:** Cultures of preservation solutions that are in contact with an organ(s) at the end of the surgical recovery should only be done if there is a question of a break in sterile technique during the procedure.

Culture reports will be obtained as soon as possible post organ recovery. All results should be final at this time. The hospital or laboratory will be asked to fax all final culture results to [redacted] main office. The culture results will be collected by administrative personnel and reviewed by the director of clinical operations or designee. The results will be uploaded to [redacted] The coordinator of record, or designee if original coordinator of record is unavailable, will be informed that the culture results are available.

The clinical coordinator will report the results as follows:
- All negative results will be uploaded to DonorNET.
- All positive results will be called or faxed/emailed to the appropriate transplant centers' patient safety contact as soon as possible but within 24 hours of receipt of results. The results will also be uploaded to DonorNet.
- All results will be faxed or emailed to the appropriate tissue/eye banks if the donor was also a tissue or eye donor.

The documentation of culture reporting will be completed in [redacted] If unable to obtain a written report, an explanation will be documented in [redacted] by the clinical coordinator or QA staff and a follow up letter from [redacted] medical director will be sent reiterating the importance of obtaining donor culture information for the safety of transplant recipients.

Potential Disease Transmission – Infection or Malignancy

1. Upon receipt of information from any agency (e.g., transplant center(s), tissue/eye banks, medical examiners, hospitals) that there is suspicion of potential donor-derived disease transmission(s), [redacted] will take the following steps:

    a. The person who received the information will obtain contact information from the transplant center.

[redacted]

POLICY NUMBER: 220
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

b. The director of clinical operations or associate director of clinical operations will be notified immediately. If they are not available, the assistant executive director or executive director will be notified.

c. [redacted] administration will communicate the reported findings to all transplant centers who received organs from the donor within 24 hours.

d. [redacted] will report a potential disease transmission to the UNOS Disease Transmission Advisory Committee within 24 hours.

e. [redacted] will fill out the OPTN potential disease transmission initial report form and submit to UNOS.

f. [redacted] will cooperate with requests and comply with timelines from involved agencies including DTAC, CDC or other agency as applicable to the specific case.

Redacted - Privilege/Privacy

From: [redacted]
Sent: Tuesday, March 12, 2019 10:22 AM
To: Redacted - Privilege/Privacy
Subject: follow-up [redacted]
Attachments: 1. RCA_CAP_AFBP150.doc; 2. [redacted] 801 QA Policy CY19newDRAFT (2).doc; 3. [redacted] 209 Medical Examiner Policy CY19newDRAFT.doc; 4. [redacted] 117 Training Policy CY19_new DRAFT.doc; 5. ME Letters.pdf; 6. March 2019 Clinical Quality meeting agenda.docx; 7. Prelim Autopsy request.docx; 8. [redacted] 220 Post Procurement Follow Up and Reporting CY19_newDRAFT.doc

Dear Redacted - Privilege/Privacy

This letter is in response to our conversation and your recent written inquiry regarding donor [redacted] from 2/18/18 with a cross-clamp time of 1344 [redacted]. This donor was an accidental death and therefore had an autopsy by the local Medical Examiner. The autopsy report was provided to [redacted] 4 months following the death of the donor and subsequent heart and liver transplantation.

At [redacted], when the medical director receives an autopsy report, he/she reviews it, and only contacts the director of clinical operations to report any findings that may indicate a communicable disease transmission. The director of clinical operations would then contact the patient safety contacts at each transplant center, the tissue and eye banks, and would follow the OPTN/UNOS DTAC protocol. If the medical director does not observe any questionable findings, then he/she dates and initials the report and gives it to the information associate or a secretary to upload into [redacted] the [redacted] web-based donor database.

On Friday morning, February 15, 2019, [redacted] received a call from a [redacted] liver TXC [redacted] transplant coordinator who stated that during the liver transplant recipient's one-year follow-up appointment, an ultrasound revealed a large liver mass. Biopsy of the mass indicated it was a germ cell tumor, possibly embryonal. The [redacted] coordinator asked if we would review our donor record to determine if this could have been donor derived. Upon review of the donor record, the medical examiner's autopsy report was reviewed and it clearly stated the donor had testicular cancer. The [redacted] medical director overlooked this critical finding when he originally viewed the Medical Examiner's autopsy report on June 11, 2018. This is the reason why the autopsy findings were not communicated to [redacted] nor UNOS/DTAC.

This became a priority issue for [redacted] as we take potential or actual disease transmission very seriously. The next business day, February 18, 2019, the medical director, the executive director, the entire management team and quality improvement committee performed a root cause analysis and developed a corrective action plan, both of which are enclosed for your review. The root cause analysis led to policy/practice changes (attached), the need for medical examiner education—which began with a letter to all of our medical examiners (attached), [redacted] staff education regarding this event and the new policies (agenda attached), and the creation of a new form called Preliminary Autopsy Request form (attached).

I wanted to also share that during our RCA, we investigated other items that were only reviewed by a single member of the team. This revealed that our medical director was the only one reviewing final pathology/biopsy readings, which are received post-procurement (like autopsy and culture reports). Given this

information, clarifications were made to our Post-Procurement Follow Up and Reporting policy so that the Medical Examiner autopsy reports and pathology/biopsy reports are now handled, like our culture reporting.

Thank you for your time on the phone last week, and for your assistance and guidance with this. Please let me know if you need anything further. If we learn anything else or if we change any additional practices, we will forward that information to you. Finally, if there is someone reviewing this who may have suggestions, we would like to hear them.

Sincerely,

[redacted]

[redacted]

[redacted]

Root Cause Analysis & Action Plan – Probable Donor Derived Cancer Transmission

Date of RCA: 2/18/19
Reference #: [redacted] **Facility:** [redacted] **Category:** Major / Sentinel Event **Team:** [redacted]

Patient History & Initial Assessment

This patient was a 20 yo brain dead organ donor at [redacted] after sustaining head injuries and a cardiac arrest following a confrontation with police officers over public, disruptive behavior classified as excited delirium. Past medical / social history obtained by the father and included mental disorders that required at least one hospitalization in a psychiatric facility, medical marijuana use, short periods of jail time due to theft, DUI, and violation of probation.

Date/Time/ Reference	Details of the Event / Timeline
2.9.18 2345 [redacted]	Patient admitted to [redacted]
2.15.18 2000 [redacted]	Referral of this patient made to [redacted] (OPO).
2.16.18 1828 [redacted]	Brain death declared.
2.16.18 1828 [redacted]	Informed the family of patient's registered decision to donate, for which they supported. The past medical and social history was obtained at this time from the father of the donor, who indicated no cancer history in the donor.
2.16.18 2040 [redacted]	[redacted] contacted the Medical Examiner (ME) who cleared the patient for organ donation, but did not permit tissue donation due to the multiple Taser markings the ME wanted to preserve.
2.16.18 2300 [redacted]	A physical assessment was done by OPC #1.
2.17.18 0930 [redacted]	A bronchoscopy was completed, unremarkable.
2.17.18 1130 [redacted]	A physical assessment was done by OPC #2 with documentation of "redness/irritation noted between the legs/scrotal area with scrotum having notable swelling".

2.17.18 1340 [redacted]	A chest, abdomen and pelvis CT was performed. "The liver, spleen, kidneys, adrenals, pancreas and gallbladder were unremarkable. Small amount of ascites, no pelvic masses or lymphadenopathy".
2.18.18 0900 [redacted]	A physical assessment was done by OPC #3 with a drawing that included scrotal swelling.
2.18.18 1230 [redacted]	The donor was taken to the OR for liver and heart recovery for transplant, and small intestine recovery for research. Organ recovery was unremarkable, and cross-clamp was at 1344 [redacted] Abdominal surgeon attestation that there were no contraindications for donation, liver TXC surgeon signature. Following organ recovery, the body was transported to the morgue to await pick up by the [redacted] Medical Examiner's office.
2.19.18 0918 [redacted]	The pathologist in the [redacted] Medical Examiner's office performed the autopsy on 2/19/18 at 0918 [redacted] According to the autopsy report, during the autopsy, "numerous hemorrhagic nodules were noted on the right testicle." Pathology later revealed right testicular embryonal carcinoma, and this was included in the final autopsy report. Also included, was a statement in all capital letters: "EVIDENCE OF MEDICAL INTERVENTION AND ORGAN PROCUREMENT". There were several other statements regarding organ recovery throughout the report.
March 2018	The [redacted] Information Associate reached out to the ME office by e-fax to inform them we were still waiting on the final autopsy report. A quick response from the ME office indicated the final report was not available, as they were still waiting on toxicology results.
6.11.18	[redacted] received the final autopsy report by U.S. Mail. The [redacted] secretary wrote the UNOS ID on the report and gave it to the Medical Director for review.
6.11.18	The [redacted] Medical Director reviewed the autopsy report, dated, initialed, and submitted it to the QA staff for scanning into the donor record. No information about the donor having testicular cancer was noted by the Medical Director.
2.15.19 0900	On the morning of February 15, **2019**, the Director of Clinical Operations received a call from a [redacted] transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI. Biopsy of the mass indicated that it was a germ cell tumor probably embryonal. It was asked by the [redacted] coordinator if we would review our donor record to determine if this could have been donor derived.
2.15.19 0930	The Director of Clinical Operations quickly began reading through the donor record and eventually found the autopsy report from the ME office that revealed testicular embryonal carcinoma. She immediately notified the Associate Executive Director who then notified the Executive Director.

2.15.19 1000-1300	Between the hours of 1000-1300 [redacted] (liver), [redacted] (heart) and DTAC were notified of the finding. During the call to [redacted] the transplant coordinator stated that the heart patient died of multi-system organ failure in November of 2018, and never demonstrated any evidence of cancer. The [redacted] liver surgeon indicated that treatment would begin for the recipient and that they reported this possible disease transmission to DTAC.
2.15.19 1605 [redacted]	The Executive Director called the Medical Director to inform him.

Questions	Details of the Event
What are the current steps in the process, as designed?	Current practice is: Medical Examiner may or may not send an autopsy report without prompting. No written requirement through policy for [redacted] to contact the Medical Examiner's office for a final autopsy report, though this has been the practice for the [redacted] Information Associate. In the medical examiner section in [redacted] web-based database, it asks whether an autopsy was done. This has a yes or no box to check (it was checked yes for this case). The autopsy report is not part of formal chart closure, i.e., a donor record can close even if an autopsy is pending. When an autopsy report is sent to [redacted] the secretary or Information Associate receives the report and sends it to the Medical Director for review. The Medical Director reviews the autopsy report for anything that could lead to a disease transmission in a transplant recipient. If there is no evidence for possible disease transmission, the Medical Director initials, dates the front page of the report, and then gives it back to clerical staff for scanning into the donor record. If there is evidence for possible disease transmission, the Medical Director notifies the Director of Clinical Operations or his/her designee. The Director of Clinical Operations or his/her designee is responsible for notifying the AED, ED, patient safety contacts at all transplant centers, tissue, and eye banks affected, and filling out the requirements of the OPTN/UNOS DTAC.
What other programs were possibly impacted as a result of this event?	[redacted] Liver Transplant [redacted] Heart Transplant OPTN/UNOS DTAC

Questions	Analysis of the Event (probable cancer transmission) Why Did it Happen?	In Our Control Yes/No	Root Cause?	Contributing Cause? Can only be "yes" if not a root cause
What steps were involved that possibly contributed to the event?	Lack of communication from ME to OPO upon findings of testicular masses and identification of cancer	No	Yes	No
	ME report arrived 4 months after the donation and subsequent transplantation	No	Yes	No
	Lack of written protocol for reviewing/receiving of ME reports	Yes	No	possible
	Medical Director overlooked cancer in report	Yes	Yes	No
	Single person review of document	Yes	Yes	No
	Lack of tracking outstanding autopsy reports	Yes	No	Yes
	Initialing only first page of autopsy report by medical director	Yes	No	possible
	Lack of education for MEs to make aware that cancer can be transmitted from donor to recipient, and that the OPO should be notified	Yes	Yes	No
Human Factors: What human factors were relevant to the outcome?	Single review of autopsy report	Yes	Yes	No
	ME education	Yes	Yes	No
Policies & Protocols: What impact did the policies related to this event have on the outcome?	Lack of a specific process outlined in policy for autopsy receipt and review	Yes	No	Yes
	Lack of a protocol for educating Medical Examiners	Yes	No	Yes

Questions	Analysis of the Event (probable cancer transmission) Why Did it Happen?	In Our Control Yes/No	Root Cause?	Contributing Cause?
Written documentation: To what degree was all necessary information available when needed? Accurate? Complete?	ME report sent to the OPO four months after the autopsy	No	Yes	No
	Medical Director practice of initialing only the first page of the autopsy report	Yes	No	Possible
	Method of receiving some autopsy reports in the mail	No	No	Possible
Oral Communication: To what degree was oral communication among participants inadequate?	Lack of communication from ME to OPO when testicular cancer was confirmed.	No	Yes	No
	Lack of communication from OPO to ME to obtain final report	Yes	No	Yes
Written/Oral Communication: What are the barriers to communication of potential risk factors?	Education of MEs	Yes	Yes	No
	Availability of autopsy reports to OPO	No	No	Yes
Staff Competency: What training systems are in place to assure adequate training/competency levels as related to this event?	ME competency with potential disease transmission and communication to the OPO	Yes	Yes	No
Staff Performance: To what degree is staff performance addressed?	Physical exam training begins during orientation and is ongoing as evidenced in our training records. [redacted] physical exam training is comparable to OPOs and tissue banks throughout the industry.	Yes	No	No
	Medical Director is trained and qualified to review autopsy reports	Yes	No	No

CORRECTIVE ACTION PLAN (CAP)

	Risk Reduction Strategies	Date Implemented	Quality Monitoring	Responsible Personnel	Completed
Action Item #1	Two clinical reviews of autopsy report. The Medical and Executive Directors, or their designees, will review every Medical Examiner autopsy (initial and final) report (and private autopsy when available) within 24 hours from receipt of the report Monday through Friday from 8am – 4:30 pm. Each page of the autopsy report will be dated and initialed by both parties. All DTAC protocols and notifications to the patient safety contacts, tissue and eye banks will take place within 24 hours of receipt of the report for those that suggest potential for disease transmission.	2/15/19	The donor record QA committee will assure that the autopsy reports have been reviewed by two clinical team members within 24 hours of receipt of the report, that each page has been dated and initialed, and that the report was scanned into the donor record and DonorNet. Finally the donor record QA committee will assure that the newly formed check box was completed in [redacted]	[redacted] QA committee	✓
	For weekend and holiday hours, the Medical Examiner autopsy reports will be received by the Director of Clinical Operations, Associate Director of Clinical Operations, Associate Executive Director or Executive Director via a common electronic inbox accessible 24 hours per day, 365 days per year. The person on-call for each weekend or holiday will review the report to assess for potential disease transmission and will report any necessary findings to DTAC, patient safety contacts, and tissue/eye banks within 24 hours of receipt of the report. The following business day, the autopsy report will be reviewed by the Medical Director or the Executive Director for final sign off/uploading.	3/20/19		IT developer [redacted]	Pending
	Practice changes will be reflected in amendments to the Donor Record Quality Assurance Policy ([redacted] 801), the Medical Examiner policy ([redacted] 209), and a checkbox will be added to [redacted] All staff will be notified of the change and given ample opportunity to ask questions.	3/18/19		[redacted]	✓
Action Item #2:	Amend [redacted] policy and procedure regarding receiving autopsy reports: Implement a backup system with the secretary and information associate receiving autopsy reports and the process for handling them. Autopsy tracking system will be developed in [redacted] A	2.26.19 3.15.19	Donor record QA committee will track receipt, review and upload of final autopsy report from the Medical Examiner into the donor record.	[redacted]	✓

	new checkbox will be added into [redacted] for private autopsies as well. When the report is received during business hours, the information associate or secretary will add the UNOS ID, date and initial, write the number of pages received, and scan into [redacted] Programming changes in [redacted] will result in an instantaneous and automated email to the medical and executive directors that there is an autopsy report to review. See Item #1 for weekend and holiday receipt of Medical Examiner autopsy reports.			[redacted] or [redacted] for programming changes.	Pending
	Practice changes will be reflected in amendments to the Donor Record Quality Assurance Policy ([redacted] 801) and the Medical Examiner policy ([redacted] 209). All staff will be notified of the change and given ample opportunity to ask questions.	2.28.19		[redacted]	✓
Action Item #3	All Medical Examiners in the [redacted] DSA will receive education from [redacted] regarding possible disease transmission from donor to recipient, and the importance of communication to the OPO of early findings, and again on the final report. This education will occur within days of this RCA, then annually or within one month of a newly appointed ME.	2/27/19	The CQI committee will be responsible for assuring documentation of newly required training by adding this to the CQI agenda once per year as an audit of training activities for Medical Examiners.	[redacted]	✓
	Specific, focused contact with ME from [redacted]	2/28/19		[redacted]	✓
	This practice change will be reflected in the Training policy ([redacted] 117). All staff will be notified of the change and given ample opportunity to ask questions.	2/28/19	Staff education and training records	[redacted]	✓
Action Item #4	Create a form that is faxed to the Medical Examiner's office within 1-3 business days that includes: 1. Upon initial autopsy, were there findings that could include possible disease transmission from organ donor to recipient: Y ☐ N ☐ 2. Please fax back to [redacted] at [redacted] 3. If the Yes box is checked, a representative from [redacted] will	2/26/19 3/15/19	The donor record QA committee will assure the fax was submitted to the ME office as evidenced by the log-in history in [redacted] [redacted] will be programmed so that the form is sent automatically to	[redacted]	✓ Pending

	contact your office within one business day of receipt. This practice change will be reflected in [redacted] the Donor Record Quality Assurance policy ([redacted] 801) and the Medical Examiner policy ([redacted] 209). All staff will be notified of the change and given ample opportunity to ask questions.	2/28/19	the ME. Training for this will be for all clinical staff and all new clinical staff from this date forward.	[redacted]	✓
Action Item #5:	Contact the Chairperson of the state of [redacted] Medical Examiner [redacted] and ask to get on the agenda for the next statewide meeting regarding potential disease transmission and the importance of communicating early and often with the OPO.	First contact by 2.26.19	Medical Examiner [redacted] agenda	[redacted]	✓
	Confirmation that [redacted] will present at next [redacted] meeting.	4/15/19	Medical Examiner [redacted] agenda	[redacted]	Pending
	Contact other OPOs about Medical Examiner follow up with preliminary and/or final autopsy reporting to ascertain if there is something with their processes that could help improve ours.	3/15/19	Report at the Director's meeting	[redacted]	Pending

[redacted]

[redacted]

POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

SUBJECT: Donor Record Quality Assurance Policy

PURPOSE: To provide guidelines regarding quality assurance as it pertains to donor record completion and to provide guidelines regarding the secure retention of all [redacted] donor files.

POLICY STATEMENT: Clinical coordinator of record is responsible for completion of all required documentation as outlined on the Donor Record Quality Assurance Checklist (in [redacted] The Record Quality Assurance Committee will meet weekly to ensure compliance with this policy. Director of Clinical Operations and the Medical Director will sign off on all completed records after the Record QA Committee has determined that the record meets document requirements. All donor records—including consented-not-recovered (CNR) cases—will be maintained in a locked electronic format within [redacted] These files will be maintained for a minimum of 10 years.

CONTENTS:

1. Completion of donor records

   a. The primary clinical coordinator of record shall be responsible for completion of all documentation data entry within the time frame outlined. All corrections or additions to initial paper documentation must be made with a single line through the altered text, initialed and dated by the individual making the correction.
   b. All initial paper documentation scanned and contained within the donor records shall be completed using ink.
   c. All initial donor paperwork items must be completed (a strike-through line of "N/A" is an acceptable entry). Any additional information that is needed to be entered after the strike thru is made will require a note in [redacted] of justification. Any fields that are blank in [redacted] after validation occurs are to be considered as intentionally left blank. Once the electronic record is validated, it is locked for changes requiring the donor record to be opened at the direction of the data quality analyst or [redacted] administration.
   d. All paper documentation will be included in the donor files as scanned electronic files in [redacted] This will include documents related to: declaration of death, consent/authorization, medical-social history, ABO, serologies, diagnostic testing, OR documentation and recipient information. When no longer needed all paper documents (after scanning into [redacted] will be deposited into the secure documentation shred receptacle.
   e. Only those [redacted] employees with a need to know shall access the contents of the donor records for purpose of modification.
   f. When access to a donor record is needed for modifications after the record has completed the QA process a staff member will need to get approval from the data quality analyst or a member of [redacted] administration
   g. With the exception of OPOs or transplant centers, when copies of a donor record are requested by non-[redacted] entities, [redacted] will always consult Legal Services before processing any request for copies of any donor record. Copies may be provided to donor/transplant entities involved with that donor.

[redacted] [redacted]

POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

h. The medical director and the executive director (or his/her designees) are responsible for reviewing the initial and final autopsy reports from the Medical Examiner or in the rare instance of a private autopsy within 24 hours of receipt. This will be evidenced by the reviewers' initialing and dating of each page of the final autopsy report, and by documenting the review in [redacted]. Any findings by the Medical Director or the Executive Director of potential communicable diseases will be reported to the Director of Clinical Operations, or his/her designee, in order to initiate the responsibilities of DTAC and contacting the transplant programs, tissue and eye banks.

During weekend and holiday hours, the Medical Examiner's autopsy reports will be received by the director of clinical operations, associate director of clinical operations, the associate executive director, or executive director via a common electronic inbox that is accessible 24 hours per day, 365 days per year. The person on-call for each weekend or holiday will review the report to assess for potential disease transmission and will report any necessary findings to DTAC, patient safety contacts, and tissue/eye banks within 24 hours of receipt of the report. The following business day, the autopsy report will be reviewed by the medical or executive director for final sign off and uploading.

2. Record Quality Assurance Committee

a. The Record QA Committee shall be comprised of the director of clinical operations, data quality analyst, information associate, secretary, and a clinical coordinator who will attend as workload permits. Other staff may be directed to participate as well.
b. The Record QA committee will meet once a week to review donor files and ensure compliance with document deadlines outlined in [redacted] under record tracking.
c. Coordinators must participate in the weekly meeting, either in person or via conference call to discuss and plan timely submission of documents and completion of electronic data entry.
d. Records with outstanding documentation will remain within the committee's weekly review, with a target date of completion set.
e. The assistant executive director, director of clinical operations or associate director of clinical operations will complete the DDR data upload and validation to UNET within the 28 day deadline imposed by UNOS.
f. The clinical coordinator or a member of the QA committee will fax to the Medical Examiner's office within 1-3 business days, the Preliminary Autopsy Request form, found on [redacted].
g. If the Medical Examiner's office returns the form with the checkbox marked yes, the medical director or his/her designee will contact the medical examiner's office within 24 hours of receipt of that information to obtain the potential communicable disease transmission information.
h. The medical director will notify the AED, ED, and then the director of clinical operations at [redacted] of the potential disease transmission from organ donor to recipient(s) so that he/she or his/her designee can begin the DTAC process and notify all patient safety contacts within the transplant programs within 24 hours of receipt of the information. Tissue and eye banks will also be notified.
~~g.~~ i. The secretary and the information associate will be crossed-trained to receive initial and final autopsy reports from the Medical Examiner's offices. This back-up system will

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[redacted] [redacted]

POLICY NUMBER: 801
CATEGORY: QUALITY
REVIEW: FEBRUARY 2020

assure all autopsy reports are received and forwarded to the medical and executive directors in a timely manner.

j. The donor record QA committee will assure that the autopsy reports have been reviewed by two clinical team members within 24 hours of receipt of the report, that each page has been dated and initialed, and that the report was scanned into the donor record and DonorNet. Finally the donor record QA committee will assure that the newly formed check box was completed in [redacted]

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Note: Most medical examiner reports received are final. Initial reports are very infrequent.

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3. Final Approval

a. When a record is completed and approved by the members of the Record QA Committee, it will be directed to [redacted] administration for final sign off.
b. Administration required for final sign-off includes the medical director and the director of clinical operations. The target goal for final approval is the chart is closed within 90 days of recovery.
c. If deficiencies are discovered, the electronic chart will remain open in the QA circulation for weekly review and correction of discrepancies.

[redacted]

POLICY NUMBER: 209
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

SUBJECT: Medical examiner cases

PURPOSE: To provide guidelines concerning organ donors under the jurisdiction of the medical examiner.

POLICY: It is the policy of [redacted] to obtain permission from the medical examiner prior to the removal of organs and tissues, in compliance with [redacted] Statute. Furthermore, it is the policy of [redacted] to develop a close working relationship based on mutual trust and collaboration to promote the release of medical examiner cases for donation. [redacted] Statutes can be found online.

CONTENTS:

1. **Obtaining Clearance for Donation from the Medical Examiner's Office:**
   The clinical coordinator is responsible for requesting permission from the medical examiner for pre-autopsy removal of specific organs and tissues from a potential donor. Clearance for tissue donation will also be requested. The initial request is made to the medical examiner **in the county or district of jurisdiction, where the death occurred.** The clinical coordinator will provide the medical examiner's office with the following information:

   a. Name/age/sex/race/cause or circumstances of death
   b. Name and address of next-of-kin if requested
   c. Synopsis of injuries including CT scan reports, x-ray reports, other diagnostic imaging reports, reports of surgical procedures if requested
   d. Time of brain death declaration/intent for DCD recovery
   e. Location of incident and law enforcement agencies involved
   f. Any further information requested by the medical examiner's office

   Note: The clinical coordinator will document in [redacted] the name of the person giving clearance for donation, the date and the time. Restrictions, if any, will be documented in the space marked "restrictions." If no restrictions are given, the clinical coordinator will document "no restrictions." The clinical coordinator is responsible for assuring that visiting surgeons comply explicitly with any limitations set forth by the medical examiner regarding this procedure.

2. **Required Blood and Body Fluid Samples:**
   On all medical examiner's cases, the clinical coordinator will provide the medical examiner with (at minimum) **2 red top blood tubes, 2 gray top blood tubes, and 1 purple top blood tube.** At the request of the medical examiner's office, the **clinical coordinator will provide one or all of the following samples:**
   a. **Pre-transfusion blood sample**
   b. **urine sample**
   c. **bile sample**

   All samples will be labeled with **donor name, date and time of sample drawn, draw location, UNOS ID, type of sample, and initials.** All specimens will be placed in a sealed bag for transport to the ME's office.

3. **Required Documentation:**
   The clinical coordinator will provide the medical examiner's office with the following documentation:
   - Copy of the [redacted] donor information including consent and the medical/social history questionnaire.
   - Hospital record documentation including history and physical, progress notes, diagnostic imaging reports, consult reports, operative reports, consults from cardiology, pulmonary, cath lab for evaluation of heart and lungs for transplant, organ procurement specific operative notes and organ biopsy reports.

[redacted]

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- The clinical coordinator, information associate, or secretary will send the Preliminary Autopsy Request form to the Medical Examiner's office within 1-3 business days.
- If the medical examiner's office returns the form with the checkbox marked yes, the information associate or secretary will notify the medical director or his/her designee who will contact the medical examiner's office within 24 hours of receipt of that information to obtain the potential communicable disease transmission information.
- The medical director will notify the director of clinical operations at [redacted] of the potential disease transmission from organ donor to recipient(s) so that he/she or his/her designee can begin the DTAC process and notify all potentially affected transplant programs' patient safety contacts, tissue and eye banks.

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4. **Photographs:**
In all medical examiner cases, the clinical coordinator will provide the ME with photographs of the donor pre-procurement for the purpose of documenting physical condition of the body prior to surgery. The following views are required for all medical examiner's cases:
   a. close-up of the head from above
   b. 1/3 view of the head and thorax from above
   c. 1/3 view of the abdomen and pelvis from above
   d. 1/3 view of lower extremities from above
   e. full head to toe from lateral view
   f. close ups of all injury sites
   g. close-ups of all tattoos, scars other identifying features

Photographs for the medical examiner will have a card with the UNOS ID and date visible within the photo and all will be stored in electronic format. This information will be provided to the medical examiner's office. Copies of medical examiner pictures will NOT be maintained in [redacted] files or equipment.

5. **Abnormal Findings:**
The medical examiner needs to be informed of any abnormal findings discovered during the procurement surgery. The clinical coordinator will first contact the AOC to review abnormal findings and instruction regarding notification to ME will occur. These findings may be provided to the medical examiner by providing appropriate documentation or contacting the ME office during the procurement surgery.
   a. Abnormal findings will be documented on a hospital progress note or the organ procurement operative note.
   b. Document in detail the specifics of the abnormal finding i.e., organ damage, capsular tears, lacerations, hematomas and retroperitoneal injuries.
   c. Organ damage that does not preclude recovery is evaluated on a case-by-case basis. The administrator on-call MUST be consulted under this circumstance. This circumstance may require a call to the ME from the operating room to report the finding or taking a photograph of the organ and providing it to the ME via standard procedure.

6. **Chain of Evidence Procedures:**
All documentation and donor samples will be provided to the ME in a secure manner that maintains chain of evidence. All documentation, photographs and donor samples will be placed into the tamper-proof medical examiner's envelope. Once all information is enclosed, the envelope is sealed and cannot be re-opened. The label for the ME envelope is filled out and placed on the front side of the envelope. The completed medical examiner's packet must remain with the body or be hand carried to the ME's office by the clinical coordinator.

[redacted] [redacted]

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7. **Medical Examiner Denial:**
The clinical coordinator will contact the AOC if the medical examiner declines the case for organ donation. The AOC will consult with [redacted] executive leadership to consider further action, including:
   a. Direct call from management to the medical examiner office
   b. Involvement of the [redacted] Medical Examiner [redacted]
   c. Direct call to the chief of the medical examiner of the involved district.

The medical examiner has final decision on clearance for donation. [redacted] is obligated to report all denials to the [redacted] Medical Examiner [redacted]

8. Medical Examiner Autopsy Reports

Medical examiner's autopsy reports come to [redacted] by email/fax or US mail. These reports may be the initial or final reports. If by US mail, the Medical Examiner report will be received Monday through Friday 8am – 4:30 pm by the information associate, secretary or designee, who will write the UNOS ID, initial and date, write the number of pages received, and upload into [redacted] This upload will generate an instantaneous automated email to the medical and executive directors that there is an autopsy report to review. The medical and executive directors, or his/her designees, will review these autopsy reports (initial and final) within 24 hours of receipt of the autopsy report to [redacted] Each page of autopsy report will be dated and initialed before given back to the information associate or the secretary for uploading into [redacted] If information in either the initial or final autopsy report suggests there is a potential for disease transmission from the donor to an organ or tissue recipient, the Medical Director and/or the Executive Director will notify the Director of Clinical Operations or his/her designee, to initiate the DTAC protocol and communication to the transplant programs' patient safety contacts, and the tissue and eye banks.

For Medical Examiner's autopsy reports that are sent by email/fax, the report will be received by the information associate, secretary, or designee Monday through Friday 8:00 am - 4:30 pm, and the process outlined in the above paragraph will be followed. For all remaining weekend or holiday hours, the associate executive director, director of clinical operations, associate director of clinical operations, or the executive director will receive the report to assure all hours are covered and any necessary reporting can be done within 24 hours of receipt of the Medical Examiner's autopsy report. The receiver of the report on the weekend or holiday hours is responsible for reviewing the autopsy report, and if necessary, following the DTAC protocol, and notifying all appropriate patient safety contacts, tissue and eye banks for any reports that suggest a potential for disease transmission from the donor to a recipient. The next business day, the medical director or executive director will review the autopsy report for final sign off/uploading.

[redacted]

POLICY NUMBER: 117
CATEGORY: ADMINISTRATIVE
REVIEW: FEBRUARY 2020

Subject: Employee Orientation and Training

Purpose: To establish guidelines for providing orientation and on-going training for [redacted] employees, contracted staff, and Medical Examiners.

Policy Statement: It is the policy of [redacted] to provide all new employees with a comprehensive orientation curriculum that covers job responsibilities, core behaviors, and information related to corporate compliance, QAPI, [redacted] policies and procedures, HIPAA, HIV/AIDS, OSHA, blood borne pathogens, environment of care, infection control, risk management, patient safety and fire safety, occupational health, hazardous materials, code of conduct and goals.

[redacted] also will provide ongoing training and [redacted] annual in-services for all employees.

All current [redacted] policies can be found on the [redacted] portal/policies and procedures. All [redacted] training checklists referenced in this policy can be found on the V-drive/training

All [redacted] Employees

1. As outlined in [redacted] Safety Policy, upon hire, all [redacted] employees shall receive education and training through [redacted] as part of their initial orientation, before reporting to [redacted] for their initial assignment, and annually thereafter. Areas of training include environment of care, infection control, HIPAA, risk management and corporate compliance. The infection control section of the educational program has information on HIV/AIDS, OSHA Bloodborne Pathogens Standard and the Tuberculosis Control Plan (see [redacted] portal), corporate compliance as covered during initial orientation provided by [redacted]

2. Documentation of completion of [redacted] new employee orientation will be kept in the employee's personnel folder.

3. Training on [redacted] Electronic Information Management System (EIMS), [redacted] is provided to [redacted] employees and contract coordinators needing access to perform their job duties through face-to-face instruction as well as webinar training, as outlined in the [redacted] EIMS policy.

4. All [redacted] employees (non-internal transfers) will spend their first day at [redacted] at [redacted] for new employee orientation and the remainder of the week at [redacted] for continuation of their orientation under the direction of the immediate supervisor and executive assistant. In accordance with the staff orientation checklist, new employees will be oriented on:
    a. Mileage reimbursement, expenses and American Express protocols

[redacted]

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b. PTO documentation
c. Procedure and policy manuals
d. Use of office equipment, such as cell phones, pagers and laptops
e. Computer access and email
f. QAPI

5. During the employee's first week at [redacted] he or she may also meet with:

- Executive director
- Assistant executive director
- Accounting personnel
- Director of donor program development
- Donor family services coordinator
- Main office administrative staff
- Medical director
- Data analyst
- Clinical operations leadership

6. Select [redacted] employees will be given 30- and 90-day, post-hire interviews by a member of the management team if the supervisor identifies the need. These interviews will assess how the employees are assimilating to their new jobs and how the actual job duties compare to how they were presented to them during their pre-employment interviews.

Individualized Staff Training

1. Clinical Coordinators

a. Clinical coordinators will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of clinical operations. No clinical coordinator will be considered fully trained until all proficiencies have been verified as completed or met by the director of clinical operations.
b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the clinical coordinator training orientation skills check list, and kept in the employee's [redacted] personnel file.
c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, real time interaction with the administrators on call, internal and external peer input, and employee assessments during educational offerings.

2. Contract Organ Procurement Coordinators

[redacted]

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CATEGORY: ADMINISTRATIVE
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a. Contract coordinators will be provided with or provide confirmation of, training that includes corporate compliance and blood borne pathogens.

3. **Family Advocates (FA)**
   a. FAs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the associate director of clinical operations/manager of family advocates. No FA will be considered fully trained until all proficiencies have been verified as completed or met by the associate director of clinical operations/manager of family advocates.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the FA checklist and kept in the employee's personnel file.
   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, real time interaction with the administrators on call, internal and external peer input, and employee assessments during educational offerings.

4. **Hospital Services Coordinators**
   a. HSCs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of donor program development (DPD). No HSC will be considered fully trained until all proficiencies have been verified as completed or met by the director of DPD.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the HSC training checklist and kept in the employee's personnel file. In accordance with the training checklist, HSCs will be oriented on:

      - Introduction to the HS process, i.e., timely donor referrals and assessments,
      - Data collection procedures
      - Marketing skills
      - Death record and variance review
      - Professional education presentation skills
      - Electronic documentation of hospital binders
      - [redacted] training

   c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, routine competency testing, internal peer feedback, external peer feedback, shadowing in the field, and deviation audits.

5. **Public Education Coordinators**

a. PECs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of donor program development (DPD). No PEC will be considered fully trained until all proficiencies have been verified as completed or met by the director DPD.
b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the PEC training checklist and kept in the employee's personnel file. In accordance with the training checklist, PEC will be oriented on:

- Public speaking and presentation skills
- Familiarity with donor family services
- Familiarity with OPO operations

c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, internal and external peer input, and routine competency testing.

6. Donor Family Service Coordinators

a. DFSCs will be trained in all areas of their job function for a period lasting approximately six months, at which time they will have completed all of their core proficiencies or have their training period extended. Training will be under the supervision of the director of DPD. No DFSC will be considered fully trained until all proficiencies have been verified as completed or met by the director of DPD.
b. Documentation of satisfactory completion of job duties and proficiencies will be documented on the DFSC training checklist and kept in the employee's personnel file. In accordance with the training checklist, DFSCs will be oriented on:

- Familiarity with OPO operations
- Familiarity with donor database and donor chart protocols
- Understanding of needs of donor families in time of grief

c. Following orientation, the methodology for identifying additional training needs will be done through the six month review, annual reviews, internal and external peer input, and routine competency testing.

7. Accounting Staff

a. Accounting staff will be trained in all areas of their job function for a period lasting approximately six months Training will be under the supervision of the executive director and other accounting staff.
b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

[redacted]

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8. **Data Management Staff**
   a. Data management staff will be trained in all areas of their job function for a period lasting approximately six months. Training will be under the supervision of the executive director and other data-related staff.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

9. **Clerical Staff**
   a. Clerical staff will be trained in all areas of their job function for a period lasting approximately six months. Training will be under the direction of their immediate supervisor and other clerical staff.
   b. Documentation of satisfactory completion of job duties and proficiencies will be documented in the employee's personnel file.

Annual and Ongoing Training

1. All [redacted] employees will complete the following mandatory inservices on an annual basis:
   - Fire safety
   - Infection control
   - HIPAA
   - Corporate compliance
   - Patient safety
   - Any other inservices as needed and requested by [redacted] and/or [redacted]

2. The OPO executive director, medical director, senior management, procurement coordinators and advisory board members will review annually the [redacted] and [redacted] policies on conflict of interest.
3. Clinical operations department employees will complete annual core competency requirements. Specific core competencies will be dictated by position. Some skills where annual core competency is demonstrated include but are not limited to:
   - Authorization
   - Obtaining medical-social history
   - Donor management
   - Packaging
   - DCD assessment

4. Ongoing training will be offered to all employees.

5. Ongoing training that offers continuing educational credits will be made available to all staff holding clinical licensure. Documentation of course completion will be kept in employee's personnel file. Supervisors will review individual training files annually

[redacted] [redacted]

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when preparing for the employee's evaluation. [redacted] will allow time off for employees to attend CEU classes.

6. All Medical Examiners in the [redacted] DSA will receive education from [redacted] regarding possible disease transmission from donor to recipient, and the importance of communication to the OPO of early findings. This education will occur annually, and will be documented in [redacted] training records. The continuous quality improvement committee will be responsible for assuring the documentation of this training.

Administrator-On-Call Training

1. Individuals identified as potential AOCs will be trained in those responsibilities by one or more of the following:

   - Medical director
   - Director of clinical operations
   - Associate director of clinical operations

2. Once an individual is proficient and can assume independent AOC responsibilities, a letter of competency will be documented by the Medical Director and placed in the employee's file.

[redacted]

February 27, 2019

[redacted]

Dear [redacted]

We are writing about an important matter and asking for your immediate help. There have been organ donor cases across the U.S. that were also ME cases, and communicable disease transmissions occurred in the organ recipients that might have been able to be treated in a more timely manner had the OPO received the ME autopsy report sooner. In a most recent case, the ME found and confirmed testicular cancer, but the report did not arrive to the OPO for 5 months due to other tests that were unrelated to the testicular cancer but possibly related to the cause of death, that delayed the report. The recipient did end up with cancer in his new organ that doctors are sure originated from the donor. We understand that there are many factors that cause delays with the ME's ability to share the final autopsy reports.

Therefore, [redacted] has created an Initial Autopsy Findings form that we will be faxing Medical Examiner's offices throughout our service area within 1 to 3 business days of an organ donor case. We have made this such that it only requires a check to a yes or no box to a single question to you that asks: upon initial autopsy if there were things that could include possible disease transmission from an organ donor to a recipient. I have attached this form for you to review. Please contact us with any questions or concerns you may have this returning this form back to us.

Our Medical Examiners are widely known as supporters of organ donation and are recognized as a key contributor to life-saving transplants. We are asking if you could help us devise a communications pathway in the rare event you discover a relevant medical concern for those patients in the course of the autopsy phase of your efforts.

The recipients of donated organs are all treated with immunosuppressive drugs to prevent rejection so communicating any potential transmissible disease in a timely manner is essential. The sooner the transplant teams know what they may have to deal with, the better the clinical outcome will be for their patients. Medical Examiners play a key role in the process of transplantation and can play a vital role in the clinical success for the patients benefiting from their cooperation.

Sincerely,

[redacted]

Medical Director,

[redacted]

Executive Director, [redacted]

DONATE LIFE

A Donate Life Organization

[redacted]

[redacted]

[redacted]

MEETING NAME	DATE/TIME
Clinical Quality meeting	March 7th

SHARED DESKTOP LINK: https://[redacted] with the password [redacted]

ATTENDEES:

AGENDA	
Opening Remarks	
QUALITY: Authorization case review Donate Life month activities: [redacted] to review Documentation for current inmate: [redacted] to review	[redacted]
AFBP150: *brief review but don't go into a lot of details now. Review following policy changes.* [redacted] **801:** *Review Initial Autopsy Findings form and when to send it.Two person autopsy review. Need to make sure that if a case isn't a ME case we are still asking the family if they are having a private autopsy and document that in* [redacted] [redacted] **117:** *updating physical exam training and will be rolling that out to all the offices very soon. ME education-* [redacted] *and* [redacted] *are setting dates with ME offices to educate* [redacted] **209:** *Initial Autopsy Findings form (goes with 801)*	[redacted]
PROCUREMENT: **Vessel ties**- *using long ties on major vessels and reminding surgeons: go over funeral home issue* **UA requirements**: *remind people to do it at OR set and UPLOAD* **Sputum gram stain**: *NEED to get one at the donor hospital PRIOR to making lung offer. Remind everyone this is minimum information for a lung offer and it has to be upload prior to hitting send on the offer!*	[redacted]

PD corrections: *if a correction is sent from PD and it has a document that needs to be corrected send that to* [redacted] *and she will put the correction thru to me.* **Label PDSA:** [redacted] *will present his practice and we will get these labels out to all offices*	
EMR updates: Access issues	[redacted]
Upcoming training/events: -OR skills training [redacted] education- mandatory -Monthly education series Clinical Education Feb- cancelled for OR training March 21- [redacted] May 16th- [redacted] tissue donation	
Staffing Updates	[redacted]
Question and Answer Session	All
Adjournment	

[redacted]

[today's date]

Dear [*Medical Examiner name*],

We are requesting preliminary information on [*donor full name*], Date of Birth [*DOB*], Date of Death [DOD], who was authorized to be an organ donor. Your office indicated to our organ procurement coordinator that an autopsy would be performed.

Upon initial autopsy, were there findings that could include possible disease transmission from organ donor to recipient?

Please check one: Yes ☐ **No** ☐

Please fax this page back to [redacted] at [redacted] as soon as possible.

If the Yes box is checked, a representative from [redacted] will contact your office within one business day of receipt.

We appreciate your assistance,

[redacted]

Ref:[*unos id*]

DONATE LIFE
A Donate Life Organization

[redacted]

[redacted] [redacted]

POLICY NUMBER: 220
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

SUBJECT: Post-Procurement Follow Up and Reporting

POLICY: The organ donor look-back policy and procedure contains information about cultures drawn during the organ donor process, the reporting of culture results to transplant centers, and potential disease transmission, infection or malignancy reporting.

PURPOSE: To provide guidelines regarding the responsibilities of the clinical coordinator and [redacted] administration concerning post-procurement follow up and reporting.

CONTENTS:

Donor Culture Reporting

1. **Blood Cultures** will be sent pre-recovery on ALL organ donors by the clinical coordinator while the donor is still in the ICU.
2. A **Urine Culture** will be sent pre-recovery on ALL donors with renal function by the clinical coordinator while the donor is still in the ICU, regardless of renal placement.
3. A **Sputum Cultures** will be sent on ALL donors where lungs are evaluated and specimens obtained.
4. **Preservation solutions:** Cultures of preservation solutions that are in contact with an organ(s) at the end of the surgical recovery should only be done if there is a question of a break in sterile technique during the procedure.

Culture reports will be obtained as soon as possible post organ recovery. ~~All results should be final at this time.~~ The ~~hospital or~~ laboratory will ~~be asked to~~ fax all final culture results to [redacted] main office. The culture results will be collected by administrative personnel Monday through Friday from 0830-1630. During weekend, night and holiday hours, the culture results will be collected by administrators on-call in order to assure all final results are received and if necessary, shared, within 24 hours of receipt. ~~and reviewed by the director of clinical operations or designee. The results will be uploaded to [redacted] The coordinator of record, or designee if original coordinator of record is unavailable, will be informed that the culture results are available.~~ All final results will be uploaded to DonorNet.

~~The clinical coordinator will report the results as follows:~~
~~-All negative results will be uploaded to DonorNET.~~
~~-All positive results will be called or faxed/emailed to the appropriate transplant centers' patient safety contact as soon as possible but within 24 hours of receipt of results. The results will also be uploaded to DonorNet.~~
~~-All results will be faxed or emailed to the appropriate tissue/eye banks if the donor was also a tissue or eye donor.~~

~~The documentation of culture reporting will be completed in [redacted] If unable to obtain a written report, an explanation will be documented in [redacted] by the clinical coordinator or QA staff and a follow up letter from [redacted] medical director will be sent reiterating the importance of obtaining donor culture information for the safety of transplant recipients.~~

Post procurement follow up and reporting of Potential Disease Transmission, ~~or~~ Infection, or Malignancy

Post procurement test results include, but are not limited to, culture results, pathology/biopsy results, medical examiner or private autopsy reports, or other laboratory reports.

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[redacted] [redacted]

POLICY NUMBER: 220
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

1. Upon receipt of information from any agency (e.g., laboratory, transplant center(s), tissue/eye banks, medical examiners, hospitals) that there is suspicion of potential donor-derived disease transmission(s), infection, or malignancy, [redacted] will take the following steps within 24 hours of receipt of the information:

   a. The person who received the information will ~~obtain contact information from the transplant center,~~ contact the director of clinical operations, assistant director of clinical operations, assistant executive director, or executive director.

   ~~b. The director of clinical operations or associate director of clinical operations will be notified immediately. If they are not available, the assistant executive director or executive director will be notified.~~

   ~~c~~b. [redacted] ~~administration will c~~Communicate the reported findings to all patient safety contacts within the transplant centers who received organs from the donor. ~~within 24 hours.~~

   ~~d~~c. [redacted] ~~will r~~Report ~~a~~the potential disease, infection, or malignancy transmission to the UNOS Disease Transmission Advisory Committee ~~within 24 hours~~.

   ~~e~~d. [redacted] ~~will fill~~Complete ~~out~~ the OPTN potential disease transmission initial report form and submit to UNOS.

   ~~f~~e. [redacted] ~~will c~~Cooperate with requests and comply with timelines from involved agencies including DTAC, CDC or other agency as applicable to the specific case.