[redacted]

From: [redacted]@indonornetwork.org>
Sent: Tuesday, June 30, 2020 12:08 PM
To: [redacted]
Cc: [redacted]
Subject: [EXTERNAL] INOP Response
Attachments: UNOS Response AHFJ065.pdf; A13.000.pdf; A11 000.pdf

Importance: High

[redacted]
Please see the attach response from INOP as requested in your letter dated June 16, 2020. Please reach out to [redacted] if you need any additional information.

Thank you,

[redacted]BA-HCA
Director, Business Analytics and Regulatory Compliance
Indiana Donor Network
[redacted]
website | REGISTER AS A DONOR

INDIANA DONOR NETWORK
Saving lives through organ and tissue donation

June 30, 2020

RE: [redacted]

Dear [redacted],

The United Network for Organ Sharing (UNOS) contacted Indiana Donor Network (INOP) on June 16, 2020 regarding donor [redacted]. In this particular case, kidneys that were recovered for transplant were inadvertently thrown in the trash, eliminating the opportunity for transplantation.

As requested, INOP is providing the additional information shown below:

Provide a detailed summary with a timeline of this event, including the following:

- **Where OPO staff were located in relation to the kidney sterile table during the events leading up to the error, and which staff member was attending to the kidneys while in the operating room;**
- **Describe any attempts to allocate the kidneys after the error;**
- **Describe all information considered when INOP ceased kidney allocation efforts;**
- **If the kidneys were able to be placed for research.**

Upon recovery of the liver and bilateral kidneys from donor [redacted] ORC [redacted] was completing liver anatomy with ORC [redacted] (orientee) in the OR while ORC [redacted] was preparing TransNet in the hallway and getting ice, which was located in the breakroom, for the shipping box. After completing the liver anatomy, ORC [redacted] went into the hallway and placed the liver in the box on ice and returned to the OR to finish kidney anatomy with ORC [redacted] The ORCs were still waiting for vessels to finalize the packing of the liver.

ORC [redacted] stepped into the OR for a few minutes to obtain nodes/spleen and observed the CST [redacted] (donor hospital employee) assisting the surgeon with liver flush/packaging. The kidneys were still being recovered at this point. ORC [redacted] returned to the hall to continue charting. The recovery surgeons from MNMC emerged from the OR and one woman asked if ORC [redacted] could escort her to the locker room so she could change out of her bloody scrubs. After escorting her down the hall, ORC [redacted] walked back to the hallway and ORC [redacted] was finalizing the packaging for the liver for transport. He vocalized that the liver and vessels were going directly on ice while the biopsy was going on top of the bag. ORC [redacted] watched and responded that it looked good. ORC [redacted] also made sure documentation made its way into the box before it was closed. Meanwhile, ORC [redacted] was trying to get the liver surgeon to sign the operative report before leaving.

Upon MNMC leaving the hospital, ORC [redacted] realized she hadn't had seen the kidneys, so she vocalized to the other ORCs that they would need to package kidneys and that she had the rigid

containers ready with ice in them. ORC [redacted] began to scrub and show ORC [redacted] how to do so as she has not seen it before. While he was doing this, ORC [redacted] was transmitting kidney anatomy to DonorNet. ORC [redacted] asked ORC [redacted] if she could make sure the OR team was keeping the kidney tables sterile as he noticed they were aggressively cleaning up.

Upon entering the OR and checking with the OR staff, ORC [redacted] reported that the kidneys were no longer on the back table, and the back table had been torn down. ORCs [redacted] and [redacted] entered the OR and asked why the sterile back table had been cleaned up. They left the OR to see if the kidneys had been placed in the cooler by the liver team by mistake. ORCs [redacted] and [redacted] went back into the OR where CST [redacted] was frantically pulling garbage out of the trash bin. It was discovered that CST [redacted] had inadvertently discarded both kidneys while tearing down sterile draping in the OR. The kidneys were recovered from the garbage bin and were noted to still be inside the three bags submerged in Servator H solution. ORC [redacted] contacted AOC [redacted] who informed Organ Manager [redacted] Organ Director [redacted] and CMO [redacted] [redacted] It was decided that they would contact the INIM transplant surgeon, [redacted], who was primary for the kidneys. Upon informing [redacted] of situation, he advised that we could not confirm whether or not the kidneys had maintained sterility while in the trash since the bags were not closed or tied. This was the same concern of INOP's CMO [redacted]; therefore, it was decided that the kidneys could not be used for transplant or research. INOP kept the kidneys for internal education and training.

01:46 – Entered the OR
02:53 – Incision time
04:43 – X-clamp time
05:00 – Liver recovered
05:04 – Liver anatomy provided
05:17 – Bilateral kidneys recovered
05:31 – Kidney anatomy provided
05:35 – ORCs [redacted] and [redacted] left the back table with kidneys on it to place the liver in a shipping container
05:35 – ORC [redacted] placed the liver in the shipping container
05:36 – ORC [redacted] returned to the back table to wait for vessels
05:39 – ORC [redacted] left the back table to place the vessels in a shipping container with the liver
05:40 – The vessels were placed in the shipping container and packaging and labeling was completed
05:45 – ORC [redacted] re-entered the OR to request escort to the ED for MNMC surgical team
05:46 – ORC [redacted] left the OR to help MNMC with the liver package, cooler, and other equipment
05:48 – MNMC surgical team departed the donor hospital
05:50 – ORCs [redacted] and [redacted] began scrubbing back in to package the kidneys that were left on the back table
05:52 – ORCs [redacted] and [redacted] noticed the OR staff cleaning and re-entered the OR
05:53 – ORC [redacted] realized the kidneys were missing
05:55 – Donor hospital CST Aaron found the kidneys in the trash
05:57 – ORC [redacted] contacted AOC [redacted] and updated him on the situation
06:00 – AOC [redacted] contacted Organ Manager [redacted] and updated him on the situation
06:08 – AOC [redacted] contacted Organ Director [redacted] and updated her on the situation
06:11 – ORC [redacted] contacted Organ Manager [redacted] to discuss how they would handle this situation
06:20 – ORC [redacted] contacted primary local transplant surgeon, [redacted] from INIM, and asked if there was anything could be done to save the kidneys (i.e., rinse them, antibiotic bath, etc.). [redacted] would not accept the kidneys and that they should not be used for transplant.

06:31 – AOC [redacted] Organ Manager [redacted], and CMO [redacted] held a conference call. [redacted] agreed that nothing could be done to salvage the kidneys for transplant.
06:46 – ORC [redacted] packaged the kidneys for research
07:00 – Exit OR time

Summarize any communication related to this event that occurred, or is planned, between INOP and others involved (i.e. OPO staff, recovering teams, donor hospital staff, donor hospital risk management team and/or leadership and the donor family).

Immediately following the incident with donor [redacted] INOP ORCs involved were asked to provide specific information and timelines leading up to the disposal of the kidneys. The donor hospital risk team was immediately informed of the event, and they were asked to conduct investigations on their end. On June 19, INOP hosted an RCA to determine how this incident occurred and where INOP and the donor hospital could change their procedures to prevent this from happening again. The Manager of Aftercare Services contacted the donor family two weeks following the recovery (as normally scheduled), and informed them that the kidneys were used for training and educational purposes.

Provide your policies and/or Standard Operating Procedures for organ recovery, labeling and packaging. Did staff follow those procedures in this case?

Enclosed are the following documents:

ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs
ORG A13.000 Packaging and Labeling of Organs

INOP staff did follow the procedures as indicated in these policies; however, ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs will be updated to define "recovery."

Provide a root cause analysis or findings of any post-case reviews, if available.

INOP hosted a RCA with the donor hospital, Community Hospital North, on June 19, 2020. The following individuals were involved in the discussion:

INOP Staff:
[redacted] Director, Business Analytics & Regulatory Compliance
[redacted] Director, Organ Services
[redacted] Director, Hospital Services
[redacted] Director, Tissue Services
[redacted] Manager, Organ Services
[redacted] Manager, Regulatory Compliance
[redacted] Manager, Process Improvement
[redacted] Manager, Hospital Services
[redacted] Manager, In-house Organ Recovery

[redacted] Organ Supervisor/AOC
[redacted] Organ Recovery Coordinator*
[redacted] Organ Recovery Coordinator*
[redacted] Organ Recovery Coordinator*
[redacted] Process Improvement Coordinator
[redacted] Process Improvement Specialist

Community Hospital North Staff:
[redacted] Administrative Coordinator
[redacted] Executive Director of Recovery Services
[redacted] Risk Manager
[redacted] OR Manager
[redacted] Nursing Manager, Surgery Department
[redacted] CST*
[redacted], Scrub, RN*

*Present in the OR

During the RCA, INOP staff and donor hospital staff went through the timeline of events leading up to the Exit OR time. The following root cause was identified:

Donor hospital staff were not aware of the fact that the recovered organs were going to multiple locations.

- The donor hospital staff was unaware that MNMC was recovering kidneys for the local transplant center, INIM.
- When MNMC left with the liver, donor hospital staff assumed the kidneys were in the same container and going to the same transplant center.
- Because the MNMC recovery team left the OR, the donor hospital CST [redacted] did not conduct a time-out prior to cleaning the back table and the rest of the OR.
- When cleaning the back table where the kidneys were, donor hospital staff assumed anything remaining was trimmed fat to be discarded.
- Donor hospital staff were rushing to clean the room to turn it over for the next surgery.

What corrective actions, if any, have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e., highlight changes, etc.).

Following the RCA, INOP and donor hospital Community Hospital North agreed that corrective actions could be implemented on both sides to ensure this does not happen again.

Community Hospital North will implement the following corrective action:

- Donor hospital Community Hospital North staff will conduct a time-out with any remaining OPO/recovery team members prior to cleaning anything in the OR.

INOP will implement the following corrective actions:

- Prior to incision, ORCs will inform the OR staff of the organs that will be recovered and that some organs may be packaged and sent for transport at different times.
- To ensure a similar incident does not occur at another donor hospital, INOP ORCs will inform the donor hospital OR team that clean-up should not begin until permission is given by the ORCs.

INOP forms F-ORG-002 Clinical Pathway Form, F-ORG-052 DCD Clinical Pathway, F-ORG-124 Expedited DCD Clinical Pathway, and F-ORG-125 Transfer Pathway will be updated to reflect these changes in practice.

If any additional information is necessary, please contact me at [redacted]

Sincerely,

[redacted]

[redacted] President/CEO

INDIANA DONOR NETWORK
Saving lives through organ and tissue donation

DEPARTMENT:	**ORG**
SECTION:	**A**
POLICY:	**11.000**
REVISION:	**16**
EFFECTIVE DATE:	**09/15/2019**

TITLE: SURGICAL RECOVERY, PERFUSION AND PRESERVATION OF ORGANS

PURPOSE:

To provide a process to facilitate and coordinate the recovery of organs to maximize utilization.

POLICY AND STANDARD OF PRACTICE:

1. Upon completion of organ allocation, the Organ Recovery Coordinator (ORC) will work with the operating room (OR) staff to set an OR time. All recovery teams, UNOS, Vital Link Donation Center (VLDC) and all local kidney transplant centers with provisional "yeses" will be notified of the OR time. Transportation will be arranged by the ORC, as needed.
2. The ORC will provide the OR staff with the Organ Recovery Surgical Supplies List Form (ORG-013) and will discuss all necessary equipment and type of recovery, e.g. brain dead donor or DCD.
3. Indiana Donor Network will be responsible for the maintenance of all sterile perfusion and preservation solutions and necessary equipment for renal and extra-renal abdominal recovery by local transplant centers. Indiana Donor Network is not responsible for thoracic perfusion but will assist as able to, when requested.
4. The ORC will assist with the transportation of the donor to the operating room, and in the proper positioning of the donor on the surgical table.
5. The entry time into the operating room, vital signs, urine output, donor management and recovery information, including anatomy of the recovered organs, will all be documented in the chart. Vital signs and urine output will be documented in 15 minute increments when possible for brain dead donors throughout the duration of the OR until cross clamp and for DCD donors until the terminal extubation occurs. After the terminal extubation the ORC will document vital signs every minute for 90 minutes or until cardiac time of death is determined. If cardiac time of death is declared by the responsible hospital physician there will then be a mandatory 5-minute wait time prior to incision, to ensure circulatory death is irreversible. During this 5-minute observation period the ORC will continue to document vitals every minute on the DCD flowsheet in iTranasplant.

6. The ORC will provide to and discuss with the Anesthesiologist, the Anesthesia Guidelines (ORG-078) or if a DCD recovery then the DCD Intraoperative Physician Guidelines (ORG-106) with the Anesthesiologist (if present) and the declaring physician and attach a copy of provided guideline into the electronic medical record. Information regarding hemodynamic goals and all routine and transplant specific medications that will be required during the recovery will be discussed.
7. The ORC will document the first and last names of all operating room personnel in the chart as well as all recovery staff from Indiana Donor Network and the various transplant centers. A list of all personnel from Indiana Donor Network and outside centers will be given to the OR staff.
8. The ORC will document all preservation solutions and additives, their lot numbers and expiration dates on the Preservation Solution Worksheet form (ORG-105) for all solutions and additives used in the recovery of organs that are not provided by Indiana Donor Network.
9. The ORC or other Indiana Donor Network personnel will be present in the operating room at all times during the recovery and will ensure that all necessary supplies are present including an appropriate amount of slush.
10. **Pre-Recovery Verification must be performed in accordance with OPTN Policy 2.14 B.** The ORC will review applicable information outlined on the **Pre-Recovery** Verification of Donor Information Form (ORG-063) **and ABO Validation Form (ORG-042)** with each surgeon and obtain their signature. The ORC will then sign, date and time the form.
11. The ORC will ensure a copy of the donor's blood type with subtyping (if used for allocation) and the donor's infectious disease testing results available at the time of organ packaging accompany each organ per Indiana Donor Network Policy ORG A13.000 Packaging and Labeling of Organs.
12. The ORC will provide each recovery team the following blood for each accepted organ unless otherwise requested: one red-top (specifically for ABO confirmation testing) and two yellow-topped tubes of blood.
13. The ORC will be responsible for assisting transplant teams with perfusion and preservation of organs as necessary.
14. The ORC will notify any transplant centers necessary, of the progress of the recovery and will specifically notify the INIM liver transplant coordinator upon visualization of the liver, if INIM is to receive the liver. An estimated arrival time for the liver will be given to the coordinator.
15. The ORC will document the cross clamp date and time, warm ischemic time, type and amount of flush solution, flush solution additives, flush characteristics, and storage solution and amount in the chart, as well as the time each organ is recovered and the organ anatomy. If there is surgical injury to any organ or associated anatomy the ORC should contact the AOC, CMO, or medical director as needed and document that discussion in a case note in the electronic medical record. A variance will need to be completed per Indiana Donor Network Policy PI A1.000 Deviation and Variance Reporting. The Manager, Organ Services or designee will complete the AOPO Surgical

Injury Collection Tool and send it to the CMO for review and follow up with the responsible transplant center. All surgical injury reports will then be quantified and reviewed again monthly and annually thereafter.

16. The ORC will periodically inform the recovery surgeon of the quantity of the preservation solution infused and the flush characteristics until directed by the recovery surgeon to discontinue the solution.
17. Cultures of preservation solutions that are in contact with the kidney(s) at the end of the recovery will be done only if there is a question of a break in sterile technique during the procedure.
18. The ORC will obtain a copy of the Anesthesiologist Record.
19. The ORC will inspect each supply prior to use and will document all supplies used, expiration dates **and** lot numbers **on Organ Case Supply Utilization form (ORG-096)**.
20. The ORC is responsible for verifying that all organs and tissues are packaged appropriately and in accordance with Policy ORG A13.000 Packaging and Labeling of Organs and will ensure each recovery surgeon signs the **Pre-Recovery** Verification of Donor Information Form (ORG-063) for each organ intended to be recovered prior to recovery.
21. Each recovery surgeon will sign a Deceased Organ Donor Operative Report (ORG-021) for each organ intended to be recovered. A copy of the Deceased Organ Donor Operative Report (ORG-021) will be left with the OR staff for the donor's hospital medical record.
22. The ORC will notify the Vital Link Donation Center of cross clamp time. This information will be communicated to the OR staff. Appropriate blood tubes will be left with the body for the eye and tissue bank recovery teams.
23. The ORC will notify one of the following or more upon completion of the recovery as deemed necessary: the Coroner, Funeral Home, Tissue Team, Family Services Coordinator (FSC), and/or appropriate hospital staff.
24. The ORC will assist in the clean-up of the OR and in post-mortem care whenever possible.
25. The ORC will make arrangements with the FSC to be with the family if they wish to see their loved one after organ recovery.
26. The ORC will document the exit OR time in the donor chart. This will be the time the hospital lists on their OR paperwork.

REFERENCES:

UNOS Policy 2.2, 2.8, 2.11, 2.12.B, 2.12.E, **2.14.B,** 16.8.A, 16.3, 16.4, 16.6, 16.6
AOPO Standards CL.4D.2.4, 6.0-6.8.9
CMS Regulation 486.344, 486.346
Indiana Donor Network Policy ORG-A13.000 Packaging and Labeling of Organs
Indiana Donor Network Policy PI-A1.000 Deviation and Variance Reporting
Indiana Donor Network Form ORG-013 Organ Recovery Surgical Supplies List Form
Indiana Donor Network Form ORG-021 Deceased Organ Donor Operative Report

Indiana Donor Network Form ORG-042 ABO Validation Form
Indiana Donor Network Form ORG-063 **Pre-Recovery** Verification of Donor Information Indiana Donor Network Form ORG-078 Anesthesia Guidelines
Indiana Donor Network Form ORG-096 Organ Case Supply Utilization
Indiana Donor Network Form ORG-105 Preservation Solution Worksheet
Indiana Donor Network Form ORG-106 DCD Intraoperative Physician Guidelines

DEPARTMENTS AFFECTED:
CMO
Family Services
Organ Services
Tissue Services
Vital Link Donation Center

INDIANA DONOR NETWORK

DEPARTMENT:	ORG
SECTION:	A
POLICY:	13.000
REVISION:	21
EFFECTIVE DATE:	11/12/2018

TITLE: PACKAGING AND LABELING OF ORGANS

PURPOSE:

To provide a process for the uniform packaging and labeling of all organs to prevent compromise of the specimens and to enhance patient safety.

POLICY AND STANDARD OF PRACTICE:

1. The Organ Recovery Coordinators (ORC) are responsible for ensuring that all organs are packaged in accordance with UNOS/OPTN policies and AOPO and CMS standards.
2. All staff handling organs and typing material will wear personal protective equipment per Indiana Donor Network Policy ADM 13.000 Universal Precautions.
3. The ORC will ensure organs are packaged and labeled according to Indiana Donor Network Work Instruction WI-ORG-057 Organ Packaging and Labeling and WI-ORG-071 Packaging and Labeling in TransNet. Each label must be verified according to the Verification of Labels on Blood Tubes, Typing Material, Vessels, & Organs Work Instruction (WI-ORG-070).
4. The ORC will ensure that the laterality of the kidney is correct, and that the ureter of the left kidney has been tagged with a piece of suture per Indiana Donor Network Work Instruction WI-ORG-057 Organ Packaging and Labeling.
5. Verification of kidney laterality will be documented in the "comments" section of the kidney anatomy page within the electronic medical record per Indiana Donor Network Work Instruction WI-ORG-057 Organ Packaging and Labeling.
6. The ORC is responsible for ensuring that the appropriate typing material and blood accompany the organ according to Indiana Donor Network Policy ORG A18.000 Serology and Tissue Typing Specimen Collection, Shipping, Reporting and Storage and that the following information is complete and packaged with each organ in a watertight container:
   a. Copy of ABOs
   b. Copy of serology results
7. **Two qualified health care professionals (one Indiana Donor Network ORC at minimum) will ensure that organ packaging is verified using the TransNet labeling system. If TransNet is unable to be used, the ORC must contact the AOC and document the reason in case notes. The ORC will then use the Verification or**

Accuracy of Documentation and Packaging of Transplantable Organs form (ORG-097) to perform this verification.

8. The ORC is responsible for ensuring all organs, tissue, blood and typing material are packaged according to UNOS policy and that all paperwork that accompanies the organ(s), tissue, blood and/or typing material adheres to UNOS policy.
9. The ORC will ensure the organ(s) is exported per Indiana Donor Network Policy ORG B5.000 Export Packaging Label Verification.
10. In the event that an organ or vessels needs sterilely repackaged an ORC is permitted to sterilely repackage the organ or vessels within the operating rooms at the donor hospital or in the **surgical recovery suites** at the Indiana Donor Network. The ORC will utilize Indiana Donor Network Work Instruction WI-ORG-057 Organ Packaging and Labeling to ensure that the organ or vessels is labeled in accordance with UNOS/OPTN policies and AOPO and CMS standards.

REFERENCES:

UNOS Policy **16.1 – 16.5**
AOPO Standards CL 6.5, **CL 6.6, CL 6.6.1, CL 6.6.2**
CMS Regulation **486.344**, 486.346
Indiana Donor Network Policy ADM 13.000 Universal Precautions
Indiana Donor Network Policy ORG A18.000 Serology and Tissue Typing Specimen Collection, Shipping, Reporting and Storage
Indiana Donor Network Policy ORG B5.000 Export Packaging Label Verification
Indiana Donor Network Work Instruction WI-ORG-057 Organ Packaging and Labeling
Indiana Donor Network Work Instruction WI-ORG-070 Verification of Labels on Blood Tubes, Typing Material, Vessels, & Organs
Indiana Donor Network Work Instruction WI-ORG-071 Packaging and Labeling in TransNet
Indiana Donor Network Form ORG-097 Verification of Accuracy of Documentation & Packaging of Transplantable Organs

DEPARTMENTS AFFECTED:

CMO
Organ Services
Regulatory Compliance