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CONFIDENTIAL MEDICAL PEER REVIEW

November 10, 2020

VIA SECURE EMAIL

[REDACTED]

OPTN Representative
CEO
Indiana Donor Network

[REDACTED]
[REDACTED]

[REDACTED]
Medical Director
Indiana Donor Network

[REDACTED]
[REDACTED]

Dear [REDACTED]

The OPTN Membership and Professional Standards Committee (MPSC) met on October 27, 2020, and reviewed a self-report that donor hospital staff inadvertently discarded both kidneys into the trash when cleaning the OR prior to Indiana Donor Network (INOP) staff returning to retrieve the kidneys for packaging. The MPSC reviewed the summary and your response, and decided that they required additional information on this event.

INOP reported three Organ Recovery Coordinators (ORCs) were involved in this donor recovery. The liver and kidneys were recovered by the procuring liver team. During organ recovery, two ORCs were primarily responsible for documentation of organ anatomy in the OR while the third ORC completed charting, labeling and packaging in the hallway. When the third ORC returned to the hallway from escorting a surgeon to the locker room, the first ORC was completing the liver packaging. After the liver team's departure, ORC 3 communicated that the kidneys needed to be packaged. At that time all three ORCs were outside of the OR. The first ORC noticed the OR being cleaned and asked the second ORC to make sure hospital staff were keeping the kidney table sterile.

Upon return to the OR, ORC 2 discovered the back table had been torn down and the kidneys discarded. Both kidneys were retrieved from the trash; triple bagged and submerged in preservation solution. The bags had not been closed. A local transplant surgeon, whose center was primary for the kidneys, expressed concern that the kidneys may not have maintained sterility while in the trash since the bags were not closed, and the OPO's CMO agreed. INOP concluded the kidneys could not be used for transplant or research but kept the kidneys for internal education and training.

INOP determined the root cause was hospital staff were unaware that the liver and kidneys were going to different locations. Hospital staff assumed the kidneys had been packaged and were taken by the liver

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team. Contributing factors were the hospital staff's rush to prepare the OR for another procedure and the absence of a time-out prior to cleaning the OR. As a corrective action, INOP added a step to their donor recovery process requiring ORCs to inform hospital OR staff prior to incision that organs may be packaged and depart for transport at different times and clean-up should not begin until permission is given by the ORCs. INOP revised its written policies to reflect this change.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee issues a Notice of Noncompliance to Indiana Donor Network for violation of Policy 2.2 (OPO Responsibilities).

FURTHER RESOLVED, that the Membership and Professional Standards Committee requests that Indiana Donor Network participate in an informal discussion with the committee.

The Committee voted 25 For; 8 Against; and 0 Abstentions.

MPSC Concerns

The MPSC appreciates INOP's self-report and its cooperation with the recovery hospital during the root cause analysis (RCA); however, reviewers were concerned by the lack of INOP senior leadership involvement in this process. Reviewers were also concerned the corrective action plan may not be effective if there is a change in hospital staff prior to the end of a case, or if organ recovery occurs at a hospital other than the one involved in this event. In addition, reviewers noted the RCA lacked acknowledgement of the OPO's responsibility to ensure the organ is packaged and accounted for throughout case.

The MPSC requests that INOP participate in an informal discussion prior to the MPSC meeting scheduled for February 23-25, 2020. Informal discussions are described in Appendix L of the OPTN Bylaws, which can be accessed on the OPTN website at [REDACTED]. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. This informal discussion will take place via conference call. If your institution wishes to participate in the informal discussion, please submit written notification to [REDACTED], Compliance Operations Analyst no later than **November 24, 2020**, to [REDACTED]@unos.org.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [REDACTED]

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Sincerely,

[REDACTED]

[REDACTED]
Chair, OPTN Membership and Professional Standards Committee

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