



CONFIDENTIAL MEDICAL PEER REVIEW

June 22, 2020

VIA SECURE EMAIL

[Redacted]
[Redacted]
Life Connection of Ohio
[Redacted]
[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 UNOS and/or OPTN Membership and Professional Standards Committee (MPSC) 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 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 malignancy evaluation and disclosure by Life Connection of Ohio (OHLC) for donor [Redacted]. Our preliminary analysis indicates that a brain biopsy collected prior to organ recovery revealed the donor had a metastasized Glioblastoma.

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

Please address the following issues related to the discovery of the donor malignancy:

- Describe the donor hospital’s communication regarding the donor’s cause of death during the allocation and procurement process. Include any notes or discussion of brain malignancy as a differential diagnosis.
- For the donor brain biopsy, describe the following:
 - When OHLC was aware that a brain biopsy had been taken;
 - When the donor hospital was aware of the initial biopsy result;
 - When OHLC was informed of the initial biopsy result;
 - Any delays in notification from the donor hospital to OHLC, and any reasons for these delays.
- Did OHLC communicate to evaluating centers any information regarding a brain biopsy or findings concerning for malignancy pre-transplant?
- DonorNet indicates that OHLC was aware the donor had a craniotomy and a head CT that could not entirely exclude an underlying mass – describe what steps OHLC took to follow-up on this testing to rule out other possible causes of death or malignancies.
- Describe what OHLC communicated to the receiving centers after being notified of the biopsy being taken.
- Describe your standard operating procedure and/or policy for evaluation of donors. Note whether this includes review of all available medical records. Did staff follow that process in this case?
- 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.).

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 OPTN 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.

[REDACTED]
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I look forward to hearing from you by July 8, 2020. Responses can be sent via mail, email and/or fax. I can be contacted at [REDACTED] or [REDACTED] or fax [REDACTED]. Thank you in advance for providing the additional information requested.

Sincerely,

[REDACTED]

[REDACTED]

[REDACTED]

UNOS Member Quality

cc:

[REDACTED]

[REDACTED]

SFC OPTN Hearing
Exhibit C.33

[REDACTED]

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Reviewer's Initials	Date of Review
[REDACTED]	6/19/20