[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

SFC OPTN Hearing
Exhibit B.20

UNOS DONATE LIFE

Member Quality Department: Non-Routine Intake and Triage Form

Staff Completing Intake: [redacted]

Mode of Notification (e.g., member complaint, self-report, observation on site survey): Member complaint

Method of Intake (e.g., phone call, site survey, PSP): [redacted]

Receipt Date (UNOS): 11/28/18 **Receipt Time (UNOS):** 8:30 am

Receipt Date (MQ): / **Receipt Time (MQ):** /

Intake Date (MQ IH Staff): / **Intake Time (MQ IH Staff):** /

Case Details

Reporting Institution or Individual: NCCM LU recipient has died

Subject of Report (Institution or Individual): SCOD

Brief Description of Issue: [redacted] 11/27/18. HR recipient (ABO B) tx w heart from hemodilated "O" donor, 1st ABO was indeterminate; following were O bA after massive transfusion. HR stiffened tedematous right after off xc, had to be converted to ECMO. They notified Scod at 0300 on 11/28/18. They + panel-test donor to be AB0 A.

Section A

1. Does the presenting issue meet any of the criteria listed on Attachment I of this document? ☒ Yes ☐ No

   AdmA 11/24
   Pronouce 11/25
   xc = 11/27

   a. If yes, describe issue below and proceed to question 2.

      #6 – Any Complaint issue...

   b. If no, proceed to question 2.

2. Was there direct and specific harm to an identified patient or patients? ☒ Yes ☐ No

   a. If yes, i. Identify the patient or patients: HR + other patients got ABO incompatible tx

      ii. Specify the harm (e.g., diagnosis, injury, condition):

      iii. When did the harm occur (date, time)? 11/27/18

      iv. Then, skip to question 4.

   b. If no, proceed to question 3.

3. Was there high potential for direct and specific harm to an identified patient or patients? ☒ Yes ☐ No

   a. If yes, i. Identify the patient or patients:

      ii. Specify the potential harm: Same as above

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iii. When did this potential for harm take place? _____

iv. Then, to question 4.

b. If no, proceed to Section B.

4. Was there a specific member action or inaction that led to the harm or the potential for harm? ☒ Yes ☐ No

a. If yes, i. State the action or inaction (be specific): ABO testing on mass transfusion

ii. Proceed to question 5.

b. If no, assign to MEDIUM PRIORITY and proceed to Case Disposition section of this form.

5. Is there a reasonable concern that this situation could recur in the near future (i.e., within 1 week)? ☐ Yes ☒ No

c. If yes, assign to HIGH PRIORITY and proceed to Case Disposition section of this form.

d. If no, assign to MEDIUM PRIORITY and proceed to Case Disposition section of this form.

Section B

6. Does the situation or issue represent a threat to the integrity or trust in the OPTN? ☒ Yes ☐ No

a. If yes, report issue within 4 hours to your Manager through direct communication (phone or face-to-face). Then, proceed to the Case Disposition section of this form.

b. If no, proceed to question 7.

7. Is there suspicion or allegation of criminal activity? ☐ Yes ☒ No

a. If yes, report issue immediately to your Manager through direct communication (phone or face-to-face). Then, proceed to the Case Disposition section of this form.

b. If no, proceed to question 8.

8. Is there media involvement? ☐ Yes ☒ No

a. If yes, send an e-mail notification to your Manager AND the DEQ Assistant Director (Audit & Monitoring).

b. If no, assign LOW PRIORITY and proceed with Routine Investigation Pathway.

Case Disposition

Intake Form must be completed within 2 hours of receipt despite assigned priority.

Initial Category Assigned:

☐ High (Your manager must be notified through direct communication immediately.)

☒ Medium (Your manager must be notified within 4 hours of intake.)

☐ Low (Your manager must review a copy of this form within 1 week of intake.)

☐ Other (Your manager must be notified immediately.)

☐ Case Referred (see list) Group: _____

Assigned Case Lead: [redacted]

Potential Policy/Bylaw Violations (if applicable): TBD

Management Review (required for all case types):

Management Notified (Date/Time): 11/28/18 9:30 am in person Management Initials: [redacted]

(In manager's absence, notify your Assistant Director.)

Category Assigned:

- ☐ High (AD/Director to notify Executive Director and Assistant Executive Director immediately. Preliminary investigation complete within 24 hours.)
- ☑ Medium (AD/Director to notify Executive Director and Assistant Executive Director within 3 days of receipt of intake.)
- ☐ Low (DEQ A.D.-Audit & Monitoring, OPTN Exec. Director and HRSA will be provided a listing of all cases designated "low" priority status on a monthly basis.)
- ☐ Other (Notify executive-level UNOS leadership within two business days of intake)

Assistant Director Review (required for high, medium and other):

Assistant Director notified (Date/Time): _____ Assistant Director Initials: _____

Agree with previously assigned category? ☐ Yes ☐ No

If no, reassigned category: ☐ High ☐Medium ☐Low ☐Other

OPTN Executive Director notified (Date/Time): _____

HRSA Notified (Date/Time): _____

☐ Included in monthly HRSA report? Month: _____

☐ Quality Inspection Complete? Date: _____ Initials: _____

Attachment 1: HRSA-Reported Events

Events that should be reported to the OPTN leadership within 24 hours of issue intake:

1. A transplant of the wrong organ into an organ recipient
2. A near-miss transplant of the wrong organ into an organ recipient
3. A transplant into the wrong organ recipient
4. A near-miss transplant into the wrong organ recipient
5. A suspected (or confirmed) human immunodeficiency virus (HIV) transmission from a donor (deceased or living) to a transplant recipient.
6. Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule.
7. A living donor death, regardless of the time period after surgery and regardless of the cause of death.
8. Failure of a native organ in a living organ donor.
9. Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records).
10. Use of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA).
11. Any "Never Event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HAC's), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation).

With respect to Items 1 and 2, an event should be considered a "near-miss" if the error is not caught before the recipient is brought to the surgery holding area. With respect to Items 1,2,3, or 4, errors that might lead to the transplant of the wrong organ or patient, or near-miss events, may include documentation errors involving donor ABO, donor identification information (ID), intended recipient name or other ID, packaging or labeling errors (of organ, tissue specimens, blood) involving donor ABO, donor ID, intended recipient name or other ID, and/or the organ type, or an organ that goes to the wrong destination.

Events that should be reported to the OPTN leadership within 1 business day (Excludes Saturday, Sunday and holidays):

1. Suspected or significant potential of (non-HIV) disease transmission from a donor to a transplant recipient.
2. Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member.

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