

Date: Wednesday, March 6 2019 11:58 AM  
Subject: RE: [REDACTED]  
From: [REDACTED]  
To: [REDACTED] <[REDACTED]unos.org>;  
CC: [REDACTED] <[REDACTED]med.miami.edu>; [REDACTED]  
[REDACTED]med.miami.edu>;  
Attachments: image004.jpg; image005.gif; image006.gif; image008.jpg; image009.jpg; image010.jpg;  
image011.jpg; 1079\_001.pdf  
Good morning [REDACTED]

Please find below answers to questions requested this morning.

1. Provide copies of your policies and procedures for the recovery of Brain Death donors and your policies and procedures for the recovery of DCD donors. Explain which of these protocols staff followed in this case.

Attached please find:

- Exhibit A, Brain Death Donor policy
- Exhibit B, The process for DCD recovery
- Exhibit C, Surgical recovery policies and procedure (DCD recovery)

The OPO's team, driven by donor family's request, followed the DCD procedures in this case, the donor was properly declared dead by neurological criteria, so no Death Note was needed at the time of recovery, however the plan is to extubate and wait for cardiac standstill. However, upon extubation, the family changed their mind and allowed recovery.

2. We have information showing that communication was made to staff at about 9:00 am the day of recovery clarifying for OPO staff that this was not a DCD donor, the donor was brain dead, and this case was just a withdrawal. Because the OPO was not considering this case to be a DCD recovery, please explain why a match was not re-run at this time.

- The donor was declared brain dead, so not death note is needed, and that was important to communicate to the staff, so there is no 2 different date/time of death by two different criteria (neurologic and circulatory), our notes repeatedly indicated that the patient was brain dead to be conducted as DCD per family's request and in accordance with UNOS policy 2.15I. Please find all notes from the OPO's staff between 8-10 AM the day of recovery, there is no indication that the OPO did not consider recovery in this case as DCD, the OPO would appreciate more details regarding the information you have regarding communication to staff.

#### Organ Allocation Comments

11/28/2018 09:53 EST

Called and spoke with Kani at Promethera to offer them a 2nd back up research offer for the Heart, Lungs, Liver, and Pancreas. They are aware of the 14:00 OR time and they will be calling us back shortly.

#### Comments: On-Site

11/28/2018 09:49 EST

\*\*\*\*\*Late Entry\*\*\*\*\* Received report from DMC [REDACTED] regarding family dynamics. Mom was asked to provide us with more time to go to OR. Mom kindly accepted to push OR Back but no longer than 14:00. She is planning to arrive at the Hospital around 13:00 and required to be explained about the process once again. She is aware that I will be here for support and willing to help family and navigate their concerns. Currently, no family at bedside DMC [REDACTED] was able to speak with OR Charge Nurse and OR was rescheduled for 14:00. HD [REDACTED] I will be heading to OR to touch bases. AOC [REDACTED] has been updated

#### Organ Allocation Comments

11/28/2018 09:41 EST

Called and spoke with [REDACTED] at 11AM and gave them a primary offer for the Heart, Lungs, and Pancreas for research and gave them a back up Liver research offer. She is aware of the 14:00 OR time and she mentioned they would be calling us back with a response shortly.

Comments: On-Site

[REDACTED]

11/28/2018 09:30 EST

Zosyn 3.375 g Q/ 6 hrs. ordered Levaquin 750 mg/ 24 hrs . ordered Fluodrocortisone 0.2 mg via IGT . ordered

Organ Allocation Comments

[REDACTED]

11/28/2018 09:17 EST

Received a call from [REDACTED] and she stated she was able to get us an extra 2 hours as per the mother which means the OR time is now set for 14:00 this afternoon. I went ahead and updated Eric at FLCC with the new OR time and that as soon as we have the Liver Bx results we would be contacting him.

Comments: On-Site

[REDACTED]

11/28/2018 09:09 EST

Received report from DMC [REDACTED] Patient stable, MIVF: 0.9ns 75 ML/HR Levophed 2 mcg/min Vasop: 0.02 units/min Vitals between Normal Limits. Last CMP and U/A documented. Liver Biopsy result pending: we will have the results in 1 hr by Pathology labs report. Huddle with ICU staff DCD process was explained to them Plan: Go to OR for Abdominal recovery as a DCD Donor. Waiting for family to arrived.

Organ Allocation Comments

[REDACTED]

11/28/2018 08:52 EST

Called and spoke with [REDACTED] at FLCC to let him know that we are working diligently to obtain the results for the Bedside Liver Bx results and that we have been communicating with pathology and that they let us know that it can be up to another hour for the results to come in. He mentioned he will bring this up to the surgeon but he cannot guarantee that they'll make a decision without the Bx results.

Organ Allocation Comments

[REDACTED]

11/28/2018 08:41 EST

Called and followed up with Rosenstiel Pathology lab about the Bedside liver Bx specimen and spoke with [REDACTED] and she stated they need at least 2 hours to have this resulted and they received the [REDACTED] about an hour ago. Will contact [REDACTED] to update her on this matter.

Comments: On-Site

[REDACTED]

11/28/2018 08:34 EST

Per nursing supervisor [REDACTED] brain death notes are approved. [REDACTED] requested call back with ME information. Dmc Orestes to follow up.

Family Dynamics

[REDACTED]

11/28/2018 08:32 EST

Attempted to call LNOK with no response. Will give report to DFA [REDACTED] for follow up.

Clinical Update

[REDACTED]

11/28/2018 08:00 EST

S: Brain dead patient s/p MVA-drowning. Family requesting DCD due to emotional reasons. See family dynamics note for further details. O/A: Hemodynamically stable Vitals WNL gtt Levophed 1-3 mcg/min Vaspressin 0.01 units/min T4 5 mcg/min MIVF NS 75 mL/hr Latest CMP, PT,PTT, INR of 05:20 continue pending \*Trend of Na to be monitored for possible Fluodrocortisone 0.2mg daily addition Most recent WBC 11.33 As discussed with MD Salama, Cefepime to be D/C and replaced with Zosyn 3.375 Q6hrs and addition of Levaquin 750 mg daily. Cultures continue pending GS + and properly covered Respiratory status improved AC 13/450/40%/+5 7.40/41/122/25.4 ABG on 40% CT of chest indicated possible ARDS with a new pneumothorax to the LL measuring 2.1 cm. Finding discussed with MD Salama. Patient is stable at this time, we will continue to monitor. Patient UOP 75-400 ml over night with one dosage of Albumin 25 + Lasix 40 mg Electrolytes (Mg and Phos) replaced per hospital electrolyte replacement protocol. IR liver biopsy completed at beside per request of FLCC. OR booked for 12:00PM, per family request. Pending: family update of case

3. Your response states that a pre-OR huddle was held at 12:11 and the case notes report that the OPO would recover as a DCD and that cardiac standstill would be documented by hospital staff. Provide a clear explanation of the decision to begin recovery prior to cardiac standstill. Include when that decision was made, how that decision was reached, and who was involved in reaching that decision.
- The decision was reached between front line staff and leadership on call that day, just after extubation (16:10) the legal next of kin (mother) and the brother exited the OR, allowed recovery and the mother became very distraught. The decision was made to proceed based on verbal agreement from the mother and brother, and the unwarranted stress for the family had the OPO requested re-intubation and more time for the purpose of re-running the match as brain dead, the OPO believes this would have certainly resulted in rescinded authorization.
4. My previous email, sent March 1, 2019, requested documentation of an authorization from the family to recover prior to cardiac death. I did not receive documentation of authorization to move forward with recovery prior to cardiac death. Did OPO staff obtain authorization to move forward prior to cardiac death?
- After the initial authorization (Exhibit D) there was no further written authorization due to the state of distress in which the donor's mother presented. Asking permission to re-intubate, re-do paperwork, and more time to re-run the match and allocate would have resulted in rescinded authorization.
5. My initial inquiry, sent on February 14, 2019, asked if a post-case review was performed in response to this event, but your responses did not address that question. Was a post-case review performed on this case?
- The OPO's leadership met on February 14<sup>th</sup> upon receipt of your letter (Exhibit E), a decision was made that the OPO will no longer proceed with brain dead donor as DCD, the decision was communicated to Family Service staff during their meeting on 2/18/2019 (Exhibit F), a policy is created (Exhibit G) affirming that the OPO will no longer proceed on brain dead donors as DCD, this policy is scheduled to be discussed with staff during General Staff (Exhibit H) and Clinical (Exhibit I) meetings on 3/18/2019 for their input, after which written communication to follow.
6. My initial inquiry also asked if any corrective actions had been developed, but your responses did not address that question. Were corrective actions developed as a result of this case?
- As stated in #6 a policy was created (Exhibit G), this policy will be discussed with the team during General Staff (Exhibit H) and Clinical (Exhibit I) meetings on 3/18/2019 for their input.

Please feel free to contact me should there be a question.

Regards,

[REDACTED]

[REDACTED]

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From: [REDACTED] <[REDACTED]unos.org>  
Sent: Wednesday, March 06, 2019 7:22 AM  
To: [REDACTED] <[REDACTED]med.miami.edu>  
Cc: [REDACTED] <[REDACTED]med.miami.edu>; [REDACTED] <[REDACTED]med.miami.edu>

**Subject:** RE: [REDACTED]

**Importance:** High

Hi [REDACTED]

Thank you for FLMP's responses to my emails regarding donor AFK [REDACTED]. I have some additional requests and questions in an effort to help clarify my understanding of this case.

1. Provide copies of your policies and procedures for the recovery of Brain Death donors and your policies and procedures for the recovery of DCD donors. Explain which of these protocols staff followed in this case.
2. We have information showing that communication was made to staff at about 9:00 am the day of recovery clarifying for OPO staff that this was not a DCD donor, the donor was brain dead, and this case was just a withdrawal. Because the OPO was not considering this case to be a DCD recovery, please explain why a match was not re-run at this time.
3. Your response states that a pre-OR huddle was held at 12:11 and the case notes report that the OPO would recover as a DCD and that cardiac standstill would be documented by hospital staff. Provide a clear explanation of the decision to begin recovery prior to cardiac standstill. Include when that decision was made, how that decision was reached, and who was involved in reaching that decision.
4. My previous email, sent March 1, 2019, requested documentation of an authorization from the family to recover prior to cardiac death. I did not receive documentation of authorization to move forward with recovery prior to cardiac death. Did OPO staff obtain authorization to move forward prior to cardiac death?
5. My initial inquiry, sent on February 14, 2019, asked if a post-case review was performed in response to this event, but your responses did not address that question. Was a post-case review performed on this case?
6. My initial inquiry also asked if any corrective actions had been developed, but your responses did not address that question. Were corrective actions developed as a result of this case?

Please provide your response no later **noon, today, 3/6/2019**. If you have additional questions, please feel free to contact me.

Sincerely,

[REDACTED]

*Safety Analyst*



*Matching organs. Saving lives.*

[REDACTED]

[REDACTED]

[REDACTED]

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CONFIDENTIAL MEDICAL PEER REVIEW CONTENT/CONFIDENTIALITY STATEMENT

# SFC OPTN Hearing Exhibit L.117

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From: [REDACTED] <[REDACTED]@med.miami.edu>  
Sent: Friday, March 1, 2019 11:55 AM  
To: [REDACTED] <[REDACTED]@unos.org>  
Cc: [REDACTED] <[REDACTED]@med.miami.edu>; [REDACTED] <[REDACTED]@med.miami.edu>  
Subject: RE: [REDACTED]

Good morning [REDACTED]

See below and let me know if you have any questions. Thank you.

1. Do you have documentation of the family authorization to proceed with recovery prior to cardiac death? If so, please provide that documentation. If you do not have documentation of that authorization, please explain why.

11/28/2018 19:00 EST

Late entry Mother [REDACTED] and brother [REDACTED] arrived at the Hospital just minutes before OR, we briefly gathered in patient's room to make the pertinent arrangements for the WDLS process. When required, we escorted patient's bed to the OR. Personalized Moment of Honor was read and then patient was extubated. We exited the OR and mom became very distraught. I deemed appropriate stay with them for family support and I was able to address their concerns about next steps since they are planning a viewing in [REDACTED]. Around 18:00 mom decided to leave and politely asked me to call them once OR finished. Received a notification from DMC Orestes with the OR outcomes. A call was placed to Brother [REDACTED] who was very grateful for our communication.

2. Your response describes a meeting with the donor hospital OR staff and Abdominal team. What time did this meeting occur?

Late entry OR 1800 11/28/2018 Summary : We have a meeting with MSMC OR staff, Abdominal team (Dr. [REDACTED], Dr. [REDACTED], Dr. [REDACTED], [REDACTED] Anesthesia, SRC, s) we discuss the procedure as instructions to be a Withdrawal in the OR per family requested before to go for recovery since this patient was pronounced BD in 11/27/2018 at 0600 am, we did not need to monitor Vitals after extubation in patient pronounced death before, everybody was in agreement and we proceed to WDLS in presence of the family inside the OR. The family was notified by myself and DFA [REDACTED] before the procedure in details and was in agreement, without complaint. Family was escorted after extubation and moment of honor to the waiting room again without complication or [REDACTED] Cross Clamp at 16:19 (Time of Cardiac death). No warm ischemia time. DFA [REDACTED] support the family before and after OR. Successfully recovery Liver and Kidneys.

Best

[REDACTED]  
[REDACTED]  
Director of Operations

Life Alliance Organ Recovery Agency | University of Miami

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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Sent: Friday, March 01, 2019 8:35 AM  
To: [REDACTED] <[REDACTED]med.miami.edu>  
Cc: [REDACTED] <[REDACTED]@med.miami.edu>; [REDACTED] <[REDACTED]med.miami.edu>  
Subject: RE: [REDACTED]  
Importance: High

Good morning, [REDACTED]

Thank you for your response to my inquiry. I have a few additional questions I'm hoping you can answer:

1. Do you have documentation of the family authorization to proceed with recovery prior to cardiac death? If so, please provide that documentation. If you do not have documentation of that authorization, please explain why.
2. Your response describes a meeting with the donor hospital OR staff and Abdominal team. What time did this meeting occur?

Please provide your response no later than **noon, today, 3/1/2019**. If you have any questions, feel free to contact me.

Thank you,

[REDACTED]  
Safety Analyst



Matching organs. Saving lives.

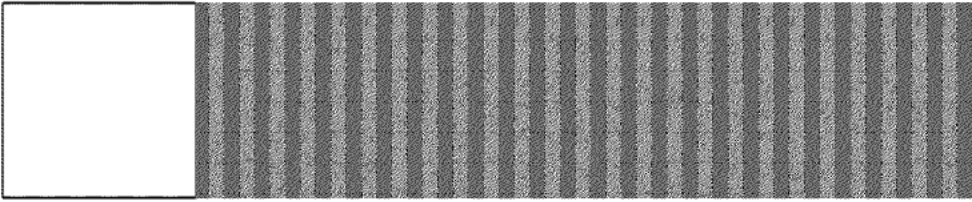


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**Cc:** [REDACTED] <[REDACTED]med.miami.edu>; [REDACTED] <[REDACTED]med.miami.edu>  
**Subject:** [REDACTED] [secure]



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