

[REDACTED]

From: [REDACTED]@lifeconnection.org>
Sent: Tuesday, July 7, 2020 10:00 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: [EXTERNAL] RE: Secure: UNOS Request for Information - OHLC - Donor [REDACTED]
Attachments: UNOS [REDACTED].pdf

Importance: High

[REDACTED]

Please see the attached document that is the follow up for the information requested for Donor [REDACTED] Please confirm that you have received this email with the attachment.

Thanks,

[REDACTED]

=====
Our email addresses have changed!
Please note our emails will now come from lifeconnection.org.
=====

The contents of this message, together with any attachments, are intended only for the use of the person(s) to whom they are addressed. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of the information contained herein is strictly prohibited. If you have received this message in error, please notify us immediately by reply electronic mail and then remove all traces of the electronic mail message from your system. Thank you.

=====



CONFIDENTIAL MEDICAL PEER REVIEW

July 7, 2020

[REDACTED]
Safety Analyst UNOS Member Quality
Organ Procurement and Transplant Network
[REDACTED]
[REDACTED]

Thank you for your inquiry. Life Connection of Ohio recognizes and takes seriously any potential disease transmission. We have reviewed donor [REDACTED] and the questions that were presented to Life Connection of Ohio and provided our responses below.

1. *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.*

Life Connection of Ohio's response: Life Connection of Ohio received this referral from St. Luke's Hospital on 3/29/2020 at 04:25 EST. The admitting diagnosis provided by the hospital RN was intracerebral hemorrhage. The RN stated that the patient also went to the operating room for a craniotomy. Life Connection of Ohio performed a medical record review of the patient on 3/29/2020 at 09:20 EST per Life Connection of Ohio Policy RS-4 (Attachment 1). During the medical record review, there was no documentation of a brain malignancy. The surgical operative report was reviewed and there was no mention of a possible brain malignancy or sending a specimen for pathological review (Attachment 2). The patient declined neurologically and was declared brain dead. No mention of brain malignancy was documented in the discharge note (Attachment 3).

2. *For the donor brain biopsy, describe the following:*
 - o When OHLC was aware that a brain biopsy had been taken;
 - o When the donor hospital was aware of the initial biopsy result;
 - o When OHLC was informed of the initial biopsy result;
 - o Any delays in notification from donor hospital to OHLC, and any reasons for these delays

Life Connection of Ohio's response: Life Connection of Ohio was made aware that a brain biopsy was taken on 4/22/2020 at 13:59 EST (Attachment 4) via email/fax from Community Tissue Services. The donor hospital (St. Luke's Hospital) per the surgical pathology report received a specimen on 3/30/2020 at 09:50 EST (Attachment 5). Within that surgical pathology report, the final diagnosis was electronically signed and verified on 04/01/2020 at 10:23 EST. Life Connection of Ohio was made aware of the initial biopsy result on 4/22/2020 at 13:59 EST (Attachment 4). Life Connection of Ohio was not made aware of the final biopsy results due to the report being signed on 4/7/2020 at 12:06 EST (Attachment 6). The Recovery Services exited the OR on 4/2/2020 at 01:08 EST. This report was final 5 days after the organ donation recovery.

Due to this patient being marked deceased and discharged the hospital did not notify the unit or attending physician.

3. *Did OHLC to communicate to evaluating centers any information regarding a brain biopsy or findings concerning for malignancy pre-transplant?*

Life Connection of Ohio's response: The match lists for liver, Pancreas/Kidney-Pancreas, Kidney, and Intestine were run on 3/31/2020 at 10:18 EST. Heart and heart/lung match lists ran on 3/31/2020 at 16:31 EST. Once these lists were run allocation started on all organs. Below is a breakdown of each organ and when the accepting center responded to the initial offer that organ becoming primary. The surgical pathology report was not verified and signed until 4/1/2020 at 10:23 EST. Life Connection of Ohio did not have any information on a biopsy to provide during allocation.

Liver – 3/31/2020 at 12:11 EST

Intestine- 3/31/2020 at 10:53 EST – List exhausted

Kidney – 3/31/2020 at 11:55 EST

Kidney- 3/31/2020 at 12:19 EST

Pancreas/Kidney-Pancreas- 3/31/2020 at 11:40 – List exhausted

Heart- 3/31/2020 at 23:09 EST

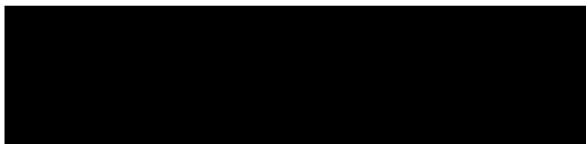
Lung – 3/31/2020 at 18:22 EST

4. *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*

Life Connection of Ohio's response: The impression from the initial Head CT w/o Contrast that was performed on 3/28/2020 at 13:24 EST stated, "Underlying mass or infarct not entirely excluded" (Attachment 7). The MRI Brain w/ and w/o Contrast that was performed on 3/28/2020 at 15:36 EST (Attachment 7) did not state underlying mass but did show the patient had a cerebral hemorrhage of uncertain etiology. The subsequent head CT performed on 3/29/2020 at 17:38 EST (Attachment 8) stated an "increase in the amount of intraventricular hemorrhage compared to the earlier exam." There was no documentation during the craniotomy that a specimen was recovered and sent for a pathological exam. The Head CT performed on 3/29/2020 showed an increase in bleeding with no underlying mass present. It also did not mention a mass was removed while compared to previous Head CT. Life Connection of Ohio was not aware of the specimen sent to pathology and the second Head CT did not state there was a mass removed based on previous Head CT.

5. *Describe what OHLC communicated to the receiving centers after being notified of the biopsy being taken.*

Life Connection of Ohio's response: Once Life Connection of Ohio was notified of the biopsy and the biopsy results Life Connection immediately notified the transplant centers who accepted each organ. Life Connection also submitted a Potential Disease Transmission Report on 4/22/2020



once all accepting transplant centers were notified. Life Connection of Ohio uploaded the Brain Biopsy report to DonorNet from the Michigan Medicine Laboratories (Attachment 9).

6. *Describe your standard operating procedure and/or policy for the evaluation of donors. Note Whether this includes review of all available medical records. Did Staff follow that process in this case?*

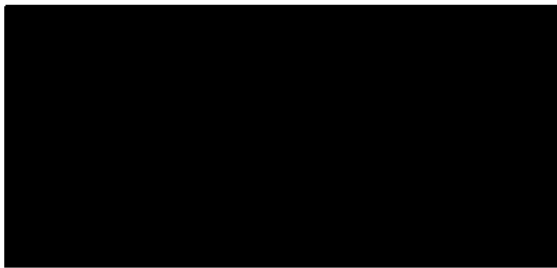
Life Connection of Ohio's response: Life Connection of Ohio follows an internal recovery policy for Donor Evaluation/ Acceptance of Donors this is Policy-RS-4 (Attachment 1). Once a PTC reviews all available medical records the PTC must enter a note within Life Connections of Ohio EMR that a medical record review was complete per Policy-RS-4. This was completed and documented within the Life Connection of Ohio's EMR (Attachment 10). Life Connection of Ohio staff completed and followed Policy-RS-4.

7. *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., highlighted changes, etc.)*

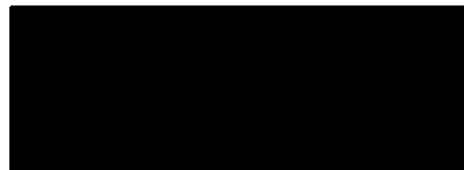
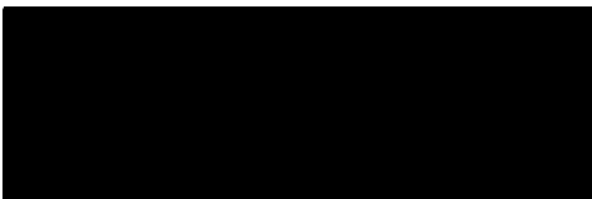
Life Connection of Ohio's response: Life Connection of Ohio recognizes the gravity of the situation and the possible disease transmission that could occur. Several areas have been addressed to prevent another occurrence. Life Connection of Ohio has updated Policy-RS-4 to include the PTC to review all pathology reports during the initial donor evaluation (Attachment 11). Life Connection of Ohio also has an updated PTC checklist within internal EMR. The checklist now has the PTC reviews all pathology reports prior to going to the OR (Attachment 12).

Please do not hesitate to reach out if you have any further questions.


Sincerely,



Enclosures (12)



ATTACHMENT 1

	Donor Evaluation / Acceptance of Donors	Document	POLICY-RS-4
		Revision	3
		Effective Date	7/17/2019
		Page Number	Page 1 of 2

POLICY:

It is the policy of Life Connection of Ohio (LCO) to respond to all potential donor referrals following LCO's *Referral Procedure* policy and perform a donor evaluation with a prompt assessment of donor suitability, which is then reported to the referring physician or nurse. It is also LCO's policy to facilitate the donation process in a manner that profoundly respects the dignity of the donor and the donor family.

PROCEDURES AND DEFINITIONS:

EVALUATION OF POTENTIAL DONORS:


LCO is responsible for performing the following activities and communicating all known information to the importing OPO or transplant center for every donor. The Procurement Transplant Coordinator (PTC) will document in LCO's electronic health record (EHR) the following, including but not limited to:

1. Name/age/sex/race
2. Date of birth
3. Medical record number
4. Referring Hospital
5. Attending Physician
6. Timeliness of referral
7. Date and time of referral
8. Date and time triggers met
9. Address (noting the zip code)
10. Social security number (if known)
11. First person status
12. Date and time of onsite arrival
13. Status of brain death declaration
14. Cause of Death
15. Family situation and status
16. Referral note that the medical chart was reviewed per POLICY-RS-4

In order to assist in the determination of donor suitability, the PTC will review the following in the donor's medical record and if found document the following, including but not limited to:

1. Past medical history: any major illnesses, surgeries, hospitalization, transfusion history, medication history, family history, and/or congenital abnormalities, recent infections, viremias, cancer, or recent inoculations/vaccinations.

ATTACHMENT 1

	Donor Evaluation / Acceptance of Donors	Document	POLICY-85-2
		Revision	3
		Effective Date	7/17/2019
		Page Number	Page 2 of 2

2. Social history: profession, smoking, any drug or alcohol use, sexual history, environmental exposures, or recent travel to foreign countries.
3. Emergent care history: EMS or Air Transport reports, pre-hospital status, cardiopulmonary arrest, etiology/circumstances of insult.
4. Current hospital course: injuries, procedures, operations, medications, and a complete history of all transfusions received since admission, fluid status, hemodynamics, vasopressors current neurological status and sedation.
5. Laboratory studies: toxicology, hematology, chemistry, urinalysis, microbiology, arterial blood gases, ABO, and serology studies.
6. Diagnostic/Radiology studies: CT, MRI, ultrasound, x-ray, and/or KUB
7. Physician progress notes

UNIQUE DONOR IDENTIFIER:

In the event a unique donor identifier is indicated, a UNOS number will be generated through UNet Secura Enterprise. A sequential OPO Identifier will also be assigned naming month, year, and sequential financial number for the donor related regional office (i.e. 01-14-01D for Dayton, 01-14-01T for Toledo). Additionally, the date of birth and or donor name may also be used as a unique identifier.

TISSUE DONOR EVALUATION:

The PTC will communicate all information obtained during donor screening and evaluation with the Donor Referral Center (DRC). The DRC will be responsible for determining final tissue/eye suitability per the appropriate tissue/eye bank criteria.

ATTACHMENT 2



Patient Name: [REDACTED]
MRN: [REDACTED]
PIN: [REDACTED]
DOB/Age/Sex: [REDACTED] 55 years Female
Admit: 3/26/2020
Disch: 4/2/2020
Admitting: [REDACTED]

Surgical Documentation

55-year-old lady with hypertension and left frontal temporal hematoma with severe mass effect and clinical deterioration suggestive of herniation syndrome. Surgery was undertaken for decompression of the brain.

Preoperative Diagnosis

Left frontal/temporal intracerebral hemorrhage

Postoperative Diagnosis

Same

Operation

1. Left frontotemporal craniotomy and evacuation of hematoma
2. Left frontal ventricular drain

Surgeon(s)

[REDACTED]

Assistant

[REDACTED]

Anesthesia

OET

Estimated Blood Loss

50 cc's

Findings

same

Specimen(s)

ICH/Clot

Technique

After induction anesthesia in a patient was already intubated, a roll was placed on the left shoulder and head was placed in Sugita tongs and secured to the table in slightly extended and turned to the right position. The entire skull was clipped, right-sided was prepped and draped in usual manner. A curvilinear incision over the left frontoparietal area was infiltrated with 0.5 percent lidocaine and 1/100000 epinephrine. This was carried down to pericranium and temporalis muscle which was dissected using Govie cautery anteriorly to the Pterion and Roney clips were applied to skin edges. Gales and muscle were retracted using fishhooks and secured to the headrest. Large frontal temporal craniotomy was then turned using the craniotome. Using small dural incision brain cannula was entered in the trajectory of the clot in the temporal and small amount of liquid clot was removed. Next the durotomy was extended anterior temporal lobe and then severe fissure was dissected under magnified vision until the clot was encountered and removed piecemeal. Small residual bleeders were controlled using bipolar cautery. The brain was slack at this point. Then dura was closed using 4 Surgilon nylon nylon frontal ventricular drain was placed and passed through a separate incision without difficulty. Bone flap was replaced using Stryker plates and screws. Muscle was closed with 200 Vicryl. Galea was closed with 3 Vicryl interrupted followed by for 0 Prolene for skin. Dressing was applied and patient was taken out of Mayfield tongs. He was then taken to the intensive care unit still intubated in stable but critical condition.

Electronically Signed on 03/28/20 10:18 PM

[REDACTED]

Neurology Procedures

Document Type: Electroencephalography EEG
Service Date/Time: 3/30/2020 00:00 EDT
Result Status: Auth (Verified)
Document Subject: Electroencephalogram (EEG)
Sign Information: [REDACTED] (3/31/2020 10:54 EDT)
[REDACTED] (3/30/2020 12:19 EDT)

Report Request ID: 34206742

Page 248 of 1,084

Print Date/Time: 4/16/2020 11:57 EDT

ATTACHMENT 3



Patient Name: [REDACTED]
MRN: [REDACTED] Admit: 3/28/2020
FIN: [REDACTED] Disch: 4/2/2020
DOB/Age/Sex: [REDACTED] 55 years Female Admitting: [REDACTED]

Discharge Documentation

Document Type: Discharge Summary
Service Date/Time: 4/7/2020 15:10 EDT
Result Status: Auth (Verified)
Document Subject: Discharge Summary
Sign Information: [REDACTED] (4/7/2020 15:15 EDT)

Admission Information

Intracranial bleed

Hospital Course

Fifty-five year female was [REDACTED] and suddenly fell on the floor. Upon her arrival to the ER patient was vomiting. Had right-sided weakness. Facial droop and left side gaze deviation. CT of the head was done showed intracranial bleed. Patient symptoms continued to deteriorate. Patient was admitted to the floor and was taken down to the OR for evacuation of hematoma. Patient obviously had been intubated by critical care prior to the surgery. Patient's condition continued here. Patient had suspicion of being brain dead. This was confirmed by Neurology. Organ donation was called and patient was taken down for organ harvesting. Patient was declared dead at 9:31 p.m. on 04/01/2020

Procedures and Treatment Provided

*Operation

1. Left frontal/temporal craniotomy and evacuation of hematoma
2. Left frontal ventricular drain

Surgeon(s)

[REDACTED]

Assistant

[REDACTED]

Performed on March 28 2020

Discharge Plan

1. Intracranial bleed I62.9
2. Cerebral edema G93.6
3. Herniation of the brain G93.6
4. Hypoxemic respiratory failure J96.91
5. Hypertension I10
6. High cholesterol E78.00
7. Hypotension I95.9

Patient Discharge Condition

Discharged by death

Discharge Disposition

Discharged by

Electronically Signed on 04/07/20 03:15 PM

[REDACTED]

ATTACHMENT 4

Re: [REDACTED]

[REDACTED]@communitytissue.org>

[REDACTED] has replied to this message on 4/22/2020 4:10 PM.

Hi [REDACTED]

There was mention of a malignant brain tumor in the hospital chart and that slides were sent to UM for further evaluation. We just followed up to make sure the further evaluation did not reveal anything of concern.

Hope this helps.

On Apr 22, 2020, at 2:37 PM, [REDACTED]@communitytissue.org wrote:

[REDACTED] this was just forwarded to me.

Do you know why this was performed? Was there suspicion?

From [REDACTED]

Sent: Wednesday, April 22, 2020 2:02 PM

To: [REDACTED]@communitytissue.org

Cc: [REDACTED]@communitytissue.org

Subject: Fwd: [REDACTED]

Get Outlook for iOS

ATTACHMENT 5



Patient Name: [REDACTED]
MRN: [REDACTED]
FIN: [REDACTED]
DOB/Age/Sex: [REDACTED] 55 years Female
Admit: 3/28/2020
Disch: 4/2/2020
Admitting: [REDACTED]

Surgical Pathology Report

Accession: S-20-0001379 Collected Date/Time: 3/28/2020 21:41 EDT Received Date/Time: 3/30/2020 09:50 EDT Pathologist: [REDACTED]

Surgical Pathology Report

Final Diagnosis

Brain, "left temporal hematoma", biopsy:
Malignant brain tumor with small cells, GFAP+ and CD56+.
Ki67 proliferative index is approximately 60%. See Comment.

Electronically signed by: [REDACTED]
Verified: 04/01/2020 10:23
NM/SH

Comment

The material will be sent to the University of Michigan for ancillary studies and final diagnostic interpretation. Intra-departmental consultation has been completed on this case.

Clinical Information

Procedure: CRANIOTOMY.
Preoperative diagnosis: HEAD PAIN, RULE OUT BRAIN TUMOR.

Specimen Source

LEFT TEMPORAL HEMATOMA

Gross Description

Received in formalin in a container labeled with the patient's name, identifiers, and "left temporal hematoma" are multiple soft dark brown and gray tissue fragments aggregating to 2.7 x 2.2 x 0.3 cm. The specimen is filtered and submitted in toto in A1. JJ/bk

Microscopic Description

One slide with H&E-stained material is examined. Immunohistochemical stains are performed with adequate controls on tissue block A1. Synaptophysin shows faint to weak staining in small tumor cells. Chromogranin is negative. CD56 is positive in small cells. Ki-67 is high (approximately 60%). Pancytokeratin, TTF-1, SOX10 and Melan-A are negative. GFAP is positive in small cells. CD45 is negative. Microscopic examination confirms the above Final Diagnosis. NM/kh

Some immunohistochemical and in situ hybridization assays use analyte specific reagents (ASR). Such assays were developed and their performance characteristics were determined by LABCORP. They have not been cleared or approved by the U. S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. These tests are used for clinical purposes. They should not be regarded as investigational or for research.

Lab

*** Clinical Documentation Content on Following Page ***

ATTACHMENT 6

Powerchart

Case:	Collected:	Received:	Requested by:
	3/26/2020 21:41 EDT	3/30/2020 9:50 EDT	

1 Surgical Pathology Report 2 Addendum Report

Status:	Date:	By:	At:
Authenticated	4/7/2020 12:06 EDT	Markelova, MD, Natalia	St Luke's

Addendum Diagnosis
The addendum is issued in order to incorporate the opinion of [REDACTED] OC-20-7948 (04/06/2020) and the results of the ancillary studies, performed at the University of Michigan.

Diagnosis:
- Brain, "left temporal hematoma", excision (St. Luke's Hospital; Maumee, OH; S-20-1379 A; 03/28/2020); Glioblastoma, IDH1 (R132H)-negative, WHO grade IV (see Comment)

Electronically signed by: [REDACTED]
Verified: 04/07/2020 12:06
IMB/KP

Comment
We have reviewed the 21 slides received for this 66-year-old woman with a brain mass. Sections shows a hypercellular glial neoplasm with angulated, atypical nuclei and eosinophilic cytoplasm. Microvascular proliferation and foci of necrosis are present. Mitotic activity is increased.

Versions... Details... Images... Print View...

< Previous Next > Close

ATTACHMENT 7



Patient Name: [REDACTED]

MRN: [REDACTED]

FIN: [REDACTED]

DOB/Age/Sex: [REDACTED] 55 years

Female

Admit: 3/28/2020

Disch: 4/2/2020

Admitting: [REDACTED]

Emergency Documentation

WS: SLHPACSDXRM2
Radimetrics Report

Signed By: [REDACTED]

CT Brain/Head w/o Contrast

03/28/20 13:24:17

IMPRESSION:

1. Apparent intraparenchymal hemorrhage which is acute medial left temporal lobe region with extension into left lateral ventricle. Mild to moderate shift of midline structures to the right noted. Ruptured middle cerebral artery aneurysm could cause this appearance. Portion of the blood may be extraparenchymal. Underlying mass or infarct not entirely excluded.

The this result was called by myself by phone to [REDACTED]
MD at 1:33 PM on 3/28/2020.

Stat reading provided.

All CT scans at this facility use dose modulation, iterative reconstruction, and/or weight based dosing when appropriate to reduce radiation dose to as low as reasonably achievable.

WS: SLHPACSDXRM2
Radimetrics Report

Signed By: [REDACTED]

MRI Brain w/ + w/o Contrast

03/28/20 15:35:59

IMPRESSION:

1. Large left cerebral hemorrhage of uncertain etiology involving the basal ganglia and portions of the frontal and temporal lobes as described above

2. There is mass effect with midline shift and compression of the basal cisterns.

3. Prominent cerebellar tonsils may represent a Chiari type I malformation.

WS: SLHPACSDXRM2

Signed By: [REDACTED]

ATTACHMENT 8

* Final Report *

Reason For Exam
swelling

CT Brain/Head w/o Contrast
History: Intracranial hemorrhage

Exam/Technique: Serial axial CT images of the brain were obtained without IV contrast. Sagittal and coronal reconstruction images were provided.

Comparison: Head CT 3/28/2020

Findings: There are post craniotomy surgical changes along the left frontal bone with interval placement of ventricular catheter with the tip directed to the fourth ventricle. There is interval decrease in size of the ventricular system especially on the right with prominent 11 mm right subfalcine shift.

There is interval effacement of the quadrigeminal plate and basal cistern with radiographic findings concerning for transtentorial herniation. There is mild increase in the degree of cerebellar tonsils herniation through the foramen magnum.

There is small amount of pneumocephalus primarily at the left anterior cranial fossa with small subarachnoid hemorrhage. There is mild increase in the amount of intraventricular hemorrhage compared to earlier exam.

The left temporal lobe parenchymal hemorrhagic changes are less prominent compared to earlier exam. However, there is interval increase in the degree of diffuse vasogenic edema with epicenter at the left temporal lobe and midbrain.

IMPRESSION: There is interval worsening with diffuse cerebral edema, effacement of quadrigeminal plate and basal cistern concerning for transtentorial herniation with increase in the cerebellar tonsils herniation through foramen magnum.

There is interval increase in the degree of vasogenic edema of the left temporal lobe and midbrain.

There is mild increase in the small amount of intraventricular hemorrhage.

There is significant decrease in the hyperdense hemorrhagic component of the left temporal lobe.

I instructed the front desk of the radiology department to deliver these findings to the referring physician.

All CT scans at this facility use dose modulation, iterative reconstruction, and/or weight based dosing when appropriate to reduce radiation dose to as low as reasonably achievable.

WS: SLHPACSTST2
Radimetrics Report

Signature Line

Transcribed by Speech Recognition: 03/29/20 05:56
Dictated by: [REDACTED] 03/29/20 05:56
Signed by: [REDACTED] 03/29/2020 06:10

ATTACHMENT 9



Michigan Medicine Laboratories



ANATOMIC PATHOLOGY CONSULTATION REPORT

Order Number: OC-20-7948 Referred by: [Redacted]
First Name: [Redacted]
Last Name: [Redacted] ST. LUKE'S HOSPITAL
MRN: [Redacted]
Gender: Female Age: 55 Y DOB: [Redacted]
Date Received: 04/02/2020 UNITED STATES
Date Completed: 04/06/2020

DIAGNOSIS:

-Brain, "left temporal hematoma", excision (St. Luke's Hospital; Maumee, OH; S-20-1379 A; 3/28/2020);

Glioblastoma, IDH1 (R132H)-negative, WHO grade IV (see comment).

Dear [Redacted]

We have reviewed the 21 slides received for this 55 year old woman with a brain mass. Sections show a hypercellular glial neoplasm with angulated, atypical nuclei, and eosinophilic cytoplasm. Microvascular proliferation and foci of necrosis are present. Mitotic activity is increased.

Immunohistochemical stains you provided show the tumor cells are positive for GFAP. They are negative for SOX-10, TTF-1, chromogranin, and Melan-A. Pankeratin shows cross reaction with glial tissue, as is commonly seen. CD68 is non-contributory. Scattered small inflammatory cells are highlighted by CD45. Synaptophysin confirms the infiltrative nature of this tumor.

Immunohistochemical stains performed at the University of Michigan for IDH1 R132H mutant-specific antibody shows negative staining in tumor cells; ATRX is retained; and p53 is negative. Ki-67 shows a proliferation index greater than 25%, and the GFAP/Ki-67 costain confirms the proliferating cells are of glial origin.

A preliminary diagnosis was communicated to you.

Thank you for sharing this case with us in consultation.

Sincerely,

First Name:
Last Name:



(Order Number: OC-20-7948)

Clinic: STLH

Page 1 of 2

ATTACHMENT 9



House Officer(s):



Materials Received:

A Outside Case Number: S-20-1379
Materials Received: Number of prepared slides: 21
Number of unstained slides: 0
Number of blocks: 1

CPT Codes:

Specimen	CPT Code	Number of Charges
A	88321	1
A	88341	3
A	88342	1
A	88343	1

Laboratory Accrediting Agency Compliance Statement:

If immunostain testing was performed on this case, the testing was developed and the performance characteristics were determined by the University of Michigan Clinical Immunoperoxidase Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. (The FDA has determined that such clearance is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research.) Appropriate negative and positive controls were run and demonstrated expected results. Most antibodies (including ER, PR, and HER2/neu) were not validated on decalcified tissues; negative staining on decalcified specimens should therefore be viewed with discretion, as a falsely negative result cannot be excluded. The Conoco AClIS statement (if used for any test on this case) is FDA approved.

Performing site:

NCRC NCRC Department of Pathology and Clinical Laboratories

CLIA Director:

CLIA Number:

First Name:




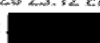
Last Name:

Printed Name: 000222


Case: STLH

Page 2 of 2

ATTACHMENT 10

	 St. Luke's Hospital	55V/E 04/01/2020 23:12 Eastern - XClamp CASE ID:  UNOS:  TISSUE ID: DBD
LCO Plan: Level 1. Will call back in a few hours and see about EEG		
Policy-RS-4 Ali Morgillo 03/29/2020 09:20 EDT		
Medical Record Reviewed per LCO Policy RS-4 is completed		
BMV Ali Morgillo 03/29/2020 09:35 EDT		
BMV checked for registration and form has been requested		

ATTACHMENT 11

	Donor Evaluation / Acceptance of Donors	Document	POLICY-RS-4
		Revision	4
		Effective Date	7/20/2020
		Page Number	Page 1 of 2

POLICY:

It is the policy of Life Connection of Ohio (LCO) to respond to all potential donor referrals following LCO's *Referral Procedure* policy and perform a donor evaluation with a prompt assessment of donor suitability, which is then reported to the referring physician or nurse. It is also LCO's policy to facilitate the donation process in a manner that profoundly respects the dignity of the donor and the donor family.

PROCEDURES AND DEFINITIONS:

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1. Name/age/sex/race
2. Date of birth
3. Medical record number
4. Referring Hospital
5. Attending Physician
6. Timeliness of referral
7. Date and time of referral
8. Date and time triggers met
9. Address (noting the zip code)
10. Social security number (if known)
11. First person status
12. Date and time of onsite arrival
13. Status of brain death declaration
14. Cause of Death
15. Family situation and status
16. Referral note that the medical chart was reviewed per POLICY-RS-4

In order to assist in the determination of donor suitability, the PTC will review the following in the donor's medical record and if found document the following, including but not limited to:

1. Past medical history: any major illnesses, surgeries, hospitalization, transfusion history, medication history, family history, and/or congenital abnormalities, recent infections, viremias, cancer, or recent inoculations/vaccinations.

ATTACHMENT 11

	Donor Evaluation / Acceptance of Donors	Document	POLICY-85-4
		Revision	4
		Effective Date	7/20/2020
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2. Social history: profession, smoking, any drug or alcohol use, sexual history, environmental exposures, or recent travel to foreign countries.
3. Emergent care history: EMS or Air Transport reports, pre-hospital status, cardiopulmonary arrest, etiology/circumstances of insult.
4. Current hospital course: injuries, procedures, operations, medications, and a complete history of all transfusions received since admission, fluid status, hemodynamics, vasopressors current neurological status and sedation.
5. Laboratory studies: toxicology, hematology, chemistry, urinalysis, microbiology, arterial blood gases, ABO, serology studies, and pathology studies.
6. Diagnostic/Radiology studies: CT, MRI, ultrasound, x-ray, and/or KUB
7. Physician progress notes

UNIQUE DONOR IDENTIFIER:

In the event a unique donor identifier is indicated, a UNOS number will be generated through UNet Secure Enterprise. A sequential OPO identifier will also be assigned naming month, year, and sequential financial number for the donor related regional office (i.e. 01-14-01D for Dayton, 01-14-01T for Toledo). Additionally, the date of birth and or donor name may also be used as a unique identifier.

TISSUE DONOR EVALUATION:

The PTC will communicate all information obtained during donor screening and evaluation with the Donor Referral Center (DRC). The DRC will be responsible for determining final tissue/eye suitability per the appropriate tissue/eye bank criteria.

ATTACHMENT 12

ORGAN ALLOCATION				
Row #	Add New	Sort Order	Description	Action
1	<input type="checkbox"/>			
2	<input type="checkbox"/>			
3		1	Attach hospital MAR to DonorNet, prior to allocation	<input checked="" type="checkbox"/>
4		2	Attach Incomplete Donor Chart- Pre OPO management to DonorNet	<input checked="" type="checkbox"/>
5		3	Fax pronouncement, DRAI, authorization, coroner's clearance, and ABO x 2 to DonorNet	<input checked="" type="checkbox"/>
6		4	If ABO blood type is A and the subtype is not used for allocation, verify the reason why it was not	<input checked="" type="checkbox"/>
7		5	If ABO types are repeatedly inconsistent, consult with Medical Director and document in Call Note	<input checked="" type="checkbox"/>
8		6	Two PTCs verify the correct entry of ABO (and subtype if applicable) into ITx and electronically sign	<input checked="" type="checkbox"/>
9		7	Document serology results in TC with verification of who entered and who verified in comment section	<input checked="" type="checkbox"/>
10		8	PTC timeout w/AOC: Review with AOC-Allocation plan and any authorization restrictions (i.e. specific	<input checked="" type="checkbox"/>
11		9	Review EMR to verify no Pathology studies are pending prior to organ allocation	<input checked="" type="checkbox"/>
12		10	Notify Medical Director of POSITIVE serologies (except CMV/EBV/Toxo), also document in Call Note	<input checked="" type="checkbox"/>
13		11	Serology Timeout: Serology Timeout: Prior to allocation, the DQS performs a third validation of s	<input checked="" type="checkbox"/>
14		12	HLA Timeout: Review HLA results with either VRL/GOLM Lab and document with call note template	<input checked="" type="checkbox"/>
15		13	*Use the Increased Risk Notification Page to document communication of Increased Risk Status.	<input checked="" type="checkbox"/>
16		14	*Ensure the liver is allocated from the liver match run. The liver must be offered through Nation	<input checked="" type="checkbox"/>
17		15	Ensure LUNG OFFERS are made within 3 hours after last CXR interpretation and ABG on 5cm H2O	<input checked="" type="checkbox"/>
18		16	If authorization is granted, ensure organs are screened for research if not suitable for transplant	<input checked="" type="checkbox"/>
19		17	*If the patient has identified risk for prion disease or exposure to HD/PGH, document notification	<input checked="" type="checkbox"/>