[redacted]

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Since 1984 — sharing organs, sharing data, sharing life.

CONFIDENTIAL MEDICAL PEER REVIEW

May 6, 2011

Certified Mail/Return Receipt Requested

[redacted]
Alabama Organ Center
[redacted]

Dear Mr. Lalisan:

I am in receipt of Corrective Action Plan correspondence dated April 20, 2011 which was submitted in response to the site review conducted at Alabama Organ Center on March 23-24, 2011. The response was prompt and thorough, and no additional information is required at this time.

The Department of Evaluation and Quality instituted a "scorecard" for evaluating site review results. The scorecard is an assessment tool used to measure an OPO's compliance with OPTN Policies. It comprises two sections, clinical and administrative.

The clinical section of the scorecard measures compliance with donor evaluation requirements, ABO verification, donor infectious disease screening, risk assessment, notification and compliance with organ packaging standards. The clinical score for Alabama Organ Center was 99 percent. The current national average for the clinical portion of the OPO scorecard is 96 percent.

The administrative section measures program compliance in the area of data validation. The administrative score for Alabama Organ Center was 88 percent. The current national average for the administrative portion of the OPO scorecard is 78 percent.

Please note that all site review results and Corrective Action Plans (CAPs) are blinded and reviewed by the OPTN/UNOS Membership and Professional Standards Committee (MPSC) on a quarterly basis. The MPSC may at that time request additional information from an OPO.

[redacted]

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I appreciate your response and the assistance of the staff at Alabama Organ Center. If you have any questions, please contact me at [redacted]

Sincerely,

[redacted]

Site Surveyor
UNOS Department of Evaluation and Quality

cc: [redacted]

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The United Network for Organ Sharing (UNOS) has a contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services, to serve as the Organ Procurement and Transplantation Network. One requirement of this contract is that UNOS conducts reviews of member organizations.

According to Title 42, Part 121 of the Code of Federal Regulations (CFR), the OPTN shall conduct "ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies."

UNOS conducted a special on-site review of at Alabama Organ Center on March 23-24, 2011.

PROGRAM BACKGROUND

The previous on-site review UNOS conducted of Alabama Organ Center was on January 13-14, 2010. Alabama Organ Center was approved for membership with UNOS on August 10, 1987 and remains a member in good standing.

REVIEW METHODOLOGY

The methodology used for conducting this site review was developed to assess compliance with the federal regulation and OPTN Policies governing the conduct of the transplantation community. UNOS Staff gave notice to [redacted] Executive Director and OPTN/UNOS Representative, and [redacted] Associate Director, on March 15, 2011 that an on-site review would take place. UNOS staff scheduled a date for the review and confirmed the date in writing on March 15, 2011. Prior to the site review, UNOS staff provided the OPO with a list of donor files for UNOS personnel to review, and a request for appropriate personnel to be available to answer any questions or assist the surveyors during the visit.

INTRODUCTION

The following report outlines the compliance results for the OPO in the following five areas:

I. Donor Record Review
   - A. Critical data review, OPTN Policies 2.2.1, 2.2.3, 2.2.4.1, 2.4, 3.2.4, 3.5.9.1, including accuracy of serology and HLA results
   - B. OPTN Policy review, OPTN Policies 2.2, 2.2.4.1- 2.2.34.6, 2.3 - 2.3.5, 2.4, 4.0, 4.5.1, 5.0
   - C. Data validation

II. Packaging demonstration, OPTN Policies 2.5, 5.1.1 - 5.5.2, 5.8.2, 5.8.3

III. Allocation issues, OPTN Policy 3.1

IV. Monthly death notification information, OPTN Policy 7.7

V. Data submission
   - A. Deceased donor registration forms, OPTN Policy 7.2
   - B. Donor organ disposition (feedback), OPTN Policy 7.5
   - C. Potential transplant recipient refusal codes, OPTN Policy 7.6

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The report ends with a summary of the audit results and areas that the OPO should address in its response. Relevant OPTN Policies are referenced throughout the report. A copy of all the OPTN Policies and Bylaws can be found at http://optn.transplant.hrsa.gov

I. Donor Record Review

A. Critical data review – donors in Attachment 1 – 20 donor records

This portion of the audit report summarizes compliance with OPTN Policies and accuracy of information submitted in UNet[SM].

- 2.2.1 Declaration of Death
- 2.2.4 Consent for organ donation
- ABO accuracy and typed twice (after 10/05/04)
- Accuracy of Serology test results recorded in donor file
- Accuracy of Human Leukocyte Antigen (HLA) test results entered in UNet[SM]

Critical data review for donors in attachment 1

20 records reviewed
20 of 20 records compliant with 2.2.1 Declaration of Death
20 of 20 records compliant with 2.2.4 Consent for organ donation
20 of 20 records compliant with and accurate for ABO
[illegible] of 20 records accurate for serology results
20 of 20 records accurate for HLA typing

Donor ID #	UNet[SM] documentation	Donor Record documentation
[redacted]	EBV IGG= Pending EBV IGM= Pending	EBV IGG= Positive EBV IGM= Negative

Requested action: Please provide a corrective action plan to ensure accurate data entry.

OPO's Response:

- **The OPO has revised the policy on refreshing serological testing results previously identified as pending to specify that EBV IgG and IgM shall be revised to positive, negative or indeterminate once the routine results are obtained. A subsequent upload of the electronic record into DonorNet shall be performed and the hard copy results shall be attached to the DonorNet record. This process shall be completed within 24 hours of the OPO receiving the results.**
- **The OPO submitted an updated copy of the policy, as well individual and collective training on this procedure shall be done by May 2, 2011.**

B. OPTN Policy review of donors in Attachment 2 - 15 donor records

This portion of the audit report analyzes the OPO's compliance with the following OPTN Policy section:

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- 2.0 Minimum Procurement Standards for an Organ Procurement Organization
- 3.2.4 Verification of the donor's ABO in UNet[SM] using source documents and ABO typing twice prior to incision
- 4.0 Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and reporting of potential recipient diseases or medical conditions, including malignancies, of donor origin
- 5.0. Standardized Packaging and Transporting of Organs and Tissue Typing Material

1. *"OPTN Policy 2.2.4*
   The Host OPO must perform the following pertinent FDA licensed, approved, or cleared serological screening tests and provide this information to the OPO or transplant center... The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors..."

   "OPTN Policy 2.2.4.1, For all potential donors:
   - *ABO typing with sub-typing for ABO-A donors;*
   - *FDA licensed Anti-HIV I, II;*
   - *CBC;*
   - *Electrolytes;*
   - *Hepatitis screening serological testing; including HBsAg, HBcAb, and Anti-HCV;*
   - *VDRL or RPR;*
   - *Anti-HTLV I/II;*
   - *Anti-CMV;*
   - *EBV serological testing;*
   - *Blood and **urine cultures**;*
   - ***Urinalysis within 24 hours prior to cross clamp**;*
   - *Arterial blood gases;*
   - *Chest x-ray;*
   - *Serum Glucose."*

2. *"OPTN Policy 2.2.4.3, For potential liver donors:*
   - *AST;*
   - *ALT;*
   - *Alkaline phosphatase;*
   - ***Direct** and total **bilirubin***
   - *INR (PT if INR not available); and*
   - *PTT."*

NOTE: Effective 5/3/3009, OPTN Policy for liver donors no longer requires a GGT

3. *"2.2.5 Follow-up on Donor Testing. The Host OPO is responsible for timely follow-up and reporting of any new or changed donor test results to the transplant program(s).*
   *The Host OPO must establish a procedure that defines its process for obtaining post-recovery donor testing results. **The Host OPO must establish and implement a process to report all positive screening or diagnostic tests received to the***

transplant center's Patient Safety Contact (as defined in Policy 4.4) within 24 hours of receipt by the OPO. The OPO must report updates such as identification of organism and sensitivity to the transplant program(s) as the OPO receives the information. If during this follow-up a new disease or malignancy is discovered in the donor that may potentially be transmitted to organ recipients, the Host OPO must report the event to the OPTN Patient Safety System, as outlined in Policy 4.5."

4. *"2.2.4 DONOR EVALUATION. Donor evaluation must be performed or coordinated by the Host OPO. All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing FDA licensed, approved, or cleared serological screening tests.* ***In the event that a required screening test is not commercially available prior to transplant, then a FDA-licensed, approved or cleared diagnostic test is permissible, and the Host OPO must document in the donor record which assay was utilized to assess the potential donor and must also provide this information to the transplant program(s).***
Exceptions: Diagnostic testing is NOT acceptable for Anti-HIV. FDA-approved diagnostic testing IS acceptable for VDRL/RPR."

Policy review for donors in attachment 2

10 of 15 compliant with 2.5.
15 of 15 compliant with 4.0
15 of 15 compliant with 5.6
Non-Compliant with OPTN Policy 2.2.4
Non-Compliant with OPTN Policy 2.2.5
Compliant with OPTN Policy 3.2.4
Compliant with OPTN Policy 4.4

While the OPO has a current policy outlining follow-up for donor testing the policy does not specify a process to report all positive screening or diagnostic tests received to the transplant center's Patient Safety Contact within 24 hours of receipt by the OPO. If during this follow-up a new disease or malignancy is discovered in the donor that may potentially be transmitted to organ recipients, the Host OPO must report the event to the OPTN Patient Safety System.

The Lab used by the OPO is using a diagnostic test for CMV IGM, EBV IGM, and EBV IGG, the surveyors were unable to verify that the OPO was documenting in the donor record which assay was utilized to assess the potential donor and that they were also providing this information to the transplant program(s).

The following donor records did not have a urine culture as required by current OPTN Policy 2.2.4.1 (former OPTN Policy 2.2.3.1).

[redacted]

The following donor records did not have a Direct Bilirubin as required by current OPTN Policy 2.2.4.3 (former OPTN Policy 2.2.3.3).

[redacted]

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The following donor records did not have a urinalysis within 24 hours of cross clamp as required by current OPTN Policy 2.2.4.1 (former OPTN Policy 2.2.3.1).

[redacted]

The following donor records did not have documentation that a serum sample has been archived as required by OPTN Policy 2.5.7.

[redacted]

Requested action: Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2.4.1, 2.2.4.3, 2.5.7, 2.2.4 and 2.2.5.

OPO's Response:

- **After reviewing the cases in which there were discrepancies in OPTN Policies 2.2.4.1 and 2.2.4.3 the OPO identified that it was an individual issue rather than a procedural issue as the same employee was identified as the lead coordinator on all three cases. Individual refresher training shall be completed no later than April 25, 2011 and a collective refresher will be completed no later than May 2, 2011.**
- **The OPO has been working with their lab to transfer the name and manufacturer of the test kits, and screening vs. diagnostic data to the preliminary serology report that is uploaded to the "Attachments" tab of the DonorNet record. As of the CAP date (April 20, 2011) the lab has provisionally accepted the following changes to the form:**
  - **A. Under each test:**
    - **a. Screening vs. diagnostic classification**
    - **b. Assay name/test kit**
    - **c. Manufacturer name**
  - **B. Added EBV IgG/IgM**
    - **a. Reflected the testing status as pending as these tests are performed at a routine, rather than STAT pace.**
  - **C. The disclosure that all tests are run in triplicate although the final interpretation is recorded as a single result. Exclude EBV IgG/IgM from the triplicate testing repetitions by clarifying the statement, 'all tests (excluding EBV IgG/IgM) were performed in triplicate'**
  - **D. Consistent with the OPO/testing facility agreement in regards to archiving serum, the technologist will now annotate that serum is archived and describe the quantity in milliliters.**

Although no specific time frame for implementation was provided from the lab as the revisions must be approved by committee, the OPO will offer all resources to assist in the rapid deployment of the revised form. The OPO submitted updated copies of their policy to reflect archiving requirements. Collective training will be completed no later than May 2, 2011.

- **The OPO has revised their policies to state that the OPO will report to their Quality Assurance Manager, or designee, and each transplant center's Patient Safety Contact any positive cultures, positive screening or diagnostic tests performed as follow-up within 24 hours of receipt by the OPO.**

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Collective re-training will be completed no later than May 2, 2011.

C. **Data Validation - donors in Attachment 3 – 10 donor records**

Validation of data submitted in Tiedi® for Deceased Donor Registration forms for donors in attachment 3

10 DDR forms reviewed
8 DDR forms with errors
23 total number of errors (Amended 21 total errors)

Donor ID	Tiedi® documentation	Donor record documentation
[redacted]	Meds within 24 hours of cross clamp: Steroids= No	Meds within 24 hours of cross clamp: Steroids= Yes **Amended-Steroids=No**
	Documentation provided-No discrepancies remain	
	Lifestyle factors: Other Hypertensive medication= Unknown	Lifestyle factors: Other Hypertensive medication= Metoprolol
[redacted]	Procurement and consent: Time consent obtained for first organ= 19:14	Procurement and consent: Time consent obtained for first organ= 17:45
	Inotropic medications at cross clamp: Vasopressin	Inotropic medications at cross clamp: Vasopressin is not an inotrope
	Pulmonary measurements: Terminal PO_2=123	Pulmonary measurements: Terminal PO_2=400 *
[redacted]	Meds within 24 hours of cross clamp: Other= Ancef	Meds within 24 hours of cross clamp: Other= Ancef, Levophed *
	Lifestyle factors: Tattoos= No Other hypertensive medications= unknown	Lifestyle factors: Tattoos= Yes * Other hypertensive medications= Yes, Lisinopril
	Organ dispositions: Liver vessels sent with organ: Yes	Organ dispositions: Liver vessels sent with organ: No **Amended- Liver vessels sent with organ=Yes**
	Documentation provided-No discrepancies remain	
[redacted]	Procurement and consent: Did the patient express to family or others the intent to be a donor= Unknown	Procurement and consent: Did the patient express to family or others the intent to be a donor= Yes, per phone consent with mother
	Inotropic medications at cross clamp: Medication= Dopamine Dosage at time of cross clamp= 9mcg/kg/min Final dosage duration= 1.2 hours Vasopressin	Inotropic medications at cross clamp: Medication= Dopamine Dosage at time of cross clamp= 7mcg/kg/min Final dosage duration= 5.7 hours Vasopressin is not an inotrope
[redacted]336	Procurement and consent: Time of pronouncement of death= 11:10	Procurement and consent: Time of pronouncement of death= 11:05

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	Inotropic medications at cross clamp: Vasopressin	Inotropic medications at cross clamp: Vasopressin is not an inotrope
[redacted]	Meds within 24 hours of cross clamp: Other= Ancef	Meds within 24 hours of cross clamp: Other= None (received last dose at 10/26 17:00) *
	Organ recovery: Right kidney final resistance= 0.39	Organ recovery: Right kidney final resistance= 0.31 *
[redacted]	Procurement and consent: Time consent obtained for first organ= 01:30	Procurement and consent: Time consent obtained for first organ= 00:32
	Meds within 24 hours of cross clamp: Steroids= Yes	Meds within 24 hours of cross clamp: Steroids= No *
	Inotropic medications at cross clamp: Medication= Dopamine Dosage at time of cross clamp= 5mcg/kg/min Final dosage duration= 4.4 hours	Inotropic medications at cross clamp: Medication= Dopamine Dosage at time of cross clamp= 5mcg/kg/min Final dosage duration= 7.25 hours
	Number of transfusions= None	Number of transfusions= 2U PRBC's *
[redacted]	Meds within 24 hours of cross clamp: Arginine Vasopressin= No Other= None	Meds within 24 hours of cross clamp: Arginine Vasopressin= Yes * Other= Epinephrine *

*** DDR's were corrected after receiving notice of on-site review, although prior to arrival on-site.**

Please note: The previous review noted 12 errors on 10 DDR forms

Requested action: Please make corrections in Tiedi® on these DDRs and submit a corrective action plan to ensure that similar errors do not occur in the future.

OPO's Response: The OPO will require staff completing DDR's to utilize the auto upload feature within their iTransplant electronic donor record system. The fields uploaded into the DDR's from iTransplant will match the fields from the DonorNet record as the iTransplant system is utilized during donor management, organ recovery and organ preservation. The Manager of Organ Recovery Services will be the responsible party for the entry of the non-uploaded fields and will conduct an initial review of the complete DDR. Then a Quality Assurance Coordinator will complete a secondary review and validate each DDR as they are completed.

Validation of data submitted for Donor Summaries in attachment 3

10 donor summaries were reviewed
9 of 10 were accurate

Donor ID	DonorNet® documentation	Donor record documentation
[redacted]	Compliant with HTN treatment= Unknown	Compliant with HTN treatment=No, per hospital record, ran out of meds several months prior

Requested action: Please provide a corrective action plan that shows how the OPO will ensure the accuracy of data entered into DonorNet®.

OPO's Response: The OPO will require staff completing DDR's to utilize the auto upload feature within their iTransplant electronic donor record system. The fields uploaded into the DDR's from iTransplant will match the fields from the DonorNet record as the iTransplant system is utilized during donor management, organ recovery and organ preservation. The Manager of Organ Recovery Services will be the responsible party for the entry of the non-uploaded fields and will conduct an initial review of the complete DDR. Then a Quality Assurance Coordinator will complete a secondary review and validate each DDR as they are completed.

II. Packaging Demonstration

UNOS Site Surveyors determined if the OPO's organ packaging supplies were in compliance with the requirements of OPTN Policy. In addition, the Site Surveyors asked OPO staff to provide a simulated demonstration of how they would package and label a kidney for shipping.

Applicable OPTN Policy 2.5.5, 2.5.6.1, 5.1.1 - 5.5.2, 5.8.2, 5.8.3

There were no areas of deficient practice identified during this demonstration.

III. Allocation issues

The UNOS Department of Evaluation and Quality conducts a 100% in-house review of all organ allocations. The UNOS Allocation Analysts review all match runs in UNet℠ and if necessary, make inquiries, when additional information is needed. The OPTN Membership and Professional Standards Committee review this information. During the site review, the UNOS Site Surveyors verify donor specific information provided by the OPO in response to inquiries by the Allocation Analysts.

There were no issues to review at this time.

IV. Monthly death notification information

UNOS Site Surveyors reviewed the OPO's methodology for reporting monthly death notification information in UNet℠ as required by OPTN Policy 7.7 Submission of Death Notification Information. UNOS Site Surveyors also determined if the OPO was using the correct definition of Eligible Donor, OPTN Policy 7.1.7, and Imminent Donor per OPTN Policy 7.1.6. Part of the review included an audit of the information submitted for a random sample of donor hospitals for the month of January 2011.

The OPO's submission for January 2011 included 22 referral classified by the OPO as "imminent". UNOS staff reviewed the referral sheets for six of these 22 referrals. UNOS staff was unable to verify if these referrals met the OPTN definition of "imminent" because the referral forms did not specify

the neurological status. Due to the lack of specific documentation, it was not possible to determine if these referrals were missing three or more brain stem reflexes. The OPO Executive Director confirmed that the OPO does not document this information on the referral forms.

"7.1.6 Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, ***upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death,*** *specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.*
Brain Stem Reflexes:
- *Pupillary reaction*
- *Response to iced caloric*
- *Gag Reflex*
- *Cough Reflex*
- *Corneal Reflex*
- *Doll's eyes reflex*
- *Response to painful stimuli*
- *Spontaneous breathing"*

UNOS site surveyors conducted a review of brain dead donors less than 71 years of age who were not reported to the OPTN as Eligible between February 25, 2010 and November 1, 2010. The sample included 24 non Eligible donors.

The referral forms for the first seven referrals documented the patient had Multi System Organ Failure. These seven donor records did not contain specific documentation to support three organs where simultaneously in failure for a period of 24 hours or more without response to treatment or resuscitation. UNOS staff requested that the OPO submit supporting documentation for the remaining 17 non eligible.

Sample Number	Donor ID	Donation Date	Donor Age	DCD? Y/N
1	[redacted]	02/19/2010	55	N
OPO provided supporting documentation				
2	[redacted]	02/26/2010	61	N
OPO provided supporting documentation				
3	[redacted]	03/02/2010	61	N
4	[redacted]	03/04/2010	69	N

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Sample Number	Donor ID	Donation Date	Donor Age	DCD? Y/N
5	[redacted]	03/17/2010	58	N
OPO provided supporting documentation				
6	[redacted]	04/30/2010	43	N
7	[redacted]	04/10/2010	19	N
OPO provided supporting documentation				
8	[redacted]	04/17/2010	63	N
OPO provided supporting documentation				
9	[redacted]	04/22/2010	40	N
OPO provided supporting documentation				
10	[redacted]	05/11/2010	61	N
OPO provided supporting documentation				
11	[redacted]	05/12/2010	63	N
OPO provided supporting documentation				
12	[redacted]	05/18/2010	54	N
OPO provided supporting documentation				
13	[redacted]	06/28/2010	27	N
14	[redacted]	06/30/2010	41	N
OPO provided supporting documentation				
15	[redacted]	06/30/2010	57	N
OPO provided supporting documentation				
16	[redacted]	06/14/2010	53	N
OPO provided supporting documentation				
17	[redacted]	07/02/2010	3	N
OPO provided supporting documentation				
18	[redacted]	07/15/2010	66	N
OPO provided supporting documentation				
19	[redacted]	07/20/2010	50	N
OPO provided supporting documentation				
20	[redacted]	08/26/2010	52	N
OPO provided supporting documentation				
21	[redacted]	09/29/2010	54	N
OPO provided supporting documentation				

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Sample Number	Donor ID	Donation Date	Donor Age	DCD? Y/N
22	[redacted]	09/13/2010	46	N
OPO provided supporting documentation				
23	[redacted]	09/15/2010	59	N
OPO provided supporting documentation				
24	[redacted]	09/18/2010	27	N
OPO provided supporting documentation				

"7.1.7 Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:
Active infections (specific diagnoses) [Exclusions to the Definition of Eligible]
Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intraabdominal sepsis, See "sepsis" below under "General"
Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV I/II, Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS
Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection
Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)
Prion: Creutzfeldt-Jacob Disease
General [Exclusions to the Definition of Eligible]: Aplastic Anemia, Agranulocytosis
Extreme Immaturity (<500 grams or gestational age of <32 weeks)
Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
Previous malignant neoplasms with current evident metastatic disease
A history of melanoma
Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma
Multi-system organ failure (MSOF) due to overwhelming sepsis or ***MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation***
Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis"

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Requested action: Please provide supporting documentation and a corrective action plan that shows how the OPO will ensure that it maintains sufficient documentation to prove imminent status or non-eligible donors.

OPO's Response: The OPO currently performs quality reviews on all heart-beating referrals on a weekly basis. The reviews are performed by administrative, clinical, education, family support and quality staff. Determination of imminent status and donor eligibility is accomplished after review of the hospital and donor records.

- **The OPO will be updating a current form in use to reflect the specific reflexes present or absent to substantiate or refute imminent status. The OPO already maintains a summary spreadsheet that can be easily accessed and reviewed for survey purposes. This spreadsheet has columns for Eligible and Imminent, which will be supported by the donor-specific form.**
- **The OPO will be updating a current form to remove the use of a UNOS refusal code for organ outcome and replace it with the justification for organ function obtained from donor management data points and medical records review. The collective review of each organ system's function based on the eligibility guidelines will be used to provide a summary of eligibility or ineligible status for the donor. The OPO is aware that future guidance on this policy is soon to be released, after receipt of this guidance they will modify their process as needed.**

The OPO will begin using the modified form beginning on May 1, 2011.

V. Data submission

An OPO's compliance with policy includes the requirements for data submission. Prior to the on-site review, UNOS Site Surveyors reviewed the OPOS's current data submission status. On March 21, 2011, the OPO's data submission was as follows:

A. Deceased donor registration forms

- There were no overdue DDR forms

B. Donor organ disposition (feedback)

- There was no overdue organ disposition (feedback)

Alabama Organ Center had the following overdue donor feedback submissions between February 5, 2010- March 10, 2011. Of 143, 140 were submitted on time (97.9%) See below for details.

Donor ID	Last Name	First Name	Clamp Date	Feedback Done Date	Difference in Business Days	Days Overdue
[redacted]	[redacted]	[redacted]	04/08/10	04/16/10	6	1
[redacted]	[redacted]	[redacted]	05/25/10	06/07/10	8	3
[redacted]	[redacted]	[redacted]	05/27/10	06/07/10	6	1

Donor feedback is to be submitted within five working days, as required by OPTN Policy 7.5, as set forth below:

*"OPTN Policy 7.5 Submission of Donor Information. Information pertaining to deceased and living **donor feedback must be submitted to UNOS within five working days of the procurement date.**"*

Requested action: Please submit a corrective action plan to ensure that donor feedback will be submitted to UNOS within five working days of the procurement date.

OPO's Response: Two members of the OPO's Quality Assurance Department are designated and responsible for submission of the donor feedback forms; there is a third employee available to assist as needed. These employees monitor the pending list each workday and plan work time to complete these by the due dates, taking into account weekends, holidays and vacations. The Quality Assurance staff utilizes a database and spreadsheet to track timelines and submission of all forms. The OPO is in the second half of a year-long self assessment of its compliance with timely submission of forms, including feedback, DDR and PTR forms.

C. Potential Transplant Recipient refusal codes

- There were no overdue Potential Transplant Recipient refusal codes

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Summary of Requested Action

For any corrective action plan submitted, provide written documentation that staff have internally reviewed such policies or procedures.

	Section of report	Requested Action and/or OPO Response
I	A. Critical data review	Please provide a corrective action plan to ensure accurate data entry. **OPO's Response:** • **The OPO has revised the policy on refreshing serological testing results previously identified as pending to specify that EBV IgG and IgM shall be revised to positive, negative or indeterminate once the routine results are obtained. A subsequent upload of the electronic record into DonorNet shall be performed and the hard copy results shall be attached to the DonorNet record. This process shall be completed within 24 hours of the OPO receiving the results.** • **The OPO submitted an updated copy of the policy, as well individual and collective training on this procedure shall be done by May 2, 2011.**
	B. OPTN Policy review	Please submit a plan of corrective action that shows how the OPO will comply with OPTN Policies 2.2.4.1, 2.2.4.3, 2.5.7, 2.2.4 and 2.2.5. in the future. **OPO's Response:** • **After reviewing the cases in which there were discrepancies in OPTN Policies 2.2.4.1 and 2.2.4.3 the OPO identified that it was an individual issue rather than a procedural issue as the same employee was identified as the lead coordinator on all three cases. Individual refresher training shall be completed no later than April 25, 2011 and a collective refresher will be completed no later than May 2, 2011.** • **The OPO has been working with their lab to transfer the name and manufacturer of the test kits, and screening vs. diagnostic data to the preliminary serology report that is uploaded to the "Attachments" tab of the DonorNet record. As of the CAP date (April 20, 2011) the lab has provisionally accepted the following changes to the form:** **E. Under each test:** **d. Screening vs. diagnostic classification** **e. Assay name/test kit** **f. Manufacturer name**

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		F. Added EBV IgG/IgM **b. Reflected the testing status as pending as these tests are performed at a routine, rather than STAT pace.** **G. The disclosure that all tests are run in triplicate although the final interpretation is recorded as a single result. Exclude EBV IgG/IgM from the triplicate testing repetitions by clarifying the statement, 'all tests (excluding EBV IgG/IgM) were performed in triplicate'** **H. Consistent with the OPO/testing facility agreement in regards to archiving serum, the technologist will now annotate that serum is archived and describe the quantity in milliliters.** **Although no specific time frame for implementation was provided from the lab as the revisions must be approved by committee, the OPO will offer all resources to assist in the rapid deployment of the revised form. The OPO submitted updated copies of their policy to reflect archiving requirements. Collective training will be completed no later than May 2, 2011.** • **The OPO has revised their policies to state that the OPO will report to their Quality Assurance Manager, or designee, and each transplant center's Patient Safety Contact any positive cultures, positive screening or diagnostic tests performed as follow-up within 24 hours of receipt by the OPO.** **Collective re-training will be completed no later than May 2, 2011.**
	C. Data validation 1. DDR forms 2. DonorNet	Please make corrections in Tiedi® and submit a corrective action plan to ensure that similar errors do not occur in the future. **<u>OPO's Response:</u> The OPO will require staff completing DDR's to utilize the auto upload feature within their iTransplant electronic donor record system. The fields uploaded into the DDR's from iTransplant will match the fields from the DonorNet record as the iTransplant system is utilized during donor management, organ recovery and organ preservation. The Manager of Organ Recovery Services will be the responsible party for the entry of the non-uploaded fields and will conduct an initial review of the complete DDR. Then a Quality Assurance Coordinator will complete a secondary review and validate each DDR as they are completed.**

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II	Allocation issues	No response needed at this time.
III	Packaging demonstration	No response needed at this time.
IV	Monthly death notification information	Please provide a corrective action plan that shows how the OPO will ensure that it submits accurate monthly death notification information in UNet[SM]. **OPO's Response: The OPO currently performs quality reviews on all heart-beating referrals on a weekly basis. The reviews are performed by administrative, clinical, education, family support and quality staff. Determination of imminent status and donor eligibility is accomplished after review of the hospital and donor records.** • **The OPO will be updating a current form in use to reflect the specific reflexes present or absent to substantiate or refute imminent status. The OPO already maintains a summary spreadsheet that can be easily accessed and reviewed for survey purposes. This spreadsheet has columns for Eligible and Imminent, which will be supported by the donor-specific form.** • **The OPO will be updating a current form to remove the use of a UNOS refusal code for organ outcome and replace it with the justification for organ function obtained from donor management data points and medical records review. The collective review of each organ system's function based on the eligibility guidelines will be used to provide a summary of eligibility or ineligible status for the donor. The OPO is aware that future guidance on this policy is soon to be released, after receipt of this guidance they will modify their process as needed.** **The OPO will begin using the modified form beginning on May 1, 2011.**
V	Data Submission	
	A. Deceased donor registration forms	No response needed at this time.
	B. Donor organ disposition (feedback)	Please submit a corrective action plan to ensure that donor feedback will be submitted to UNOS within five working days of the procurement date. **OPO's Response: Two members of the OPO's Quality Assurance Department are designated and responsible for submission of the donor feedback forms; there is a third employee available to assist as needed. These employees monitor the pending list each workday and plan work time to complete these by the due dates, taking into account weekends, holidays and vacations. The Quality Assurance staff utilizes a database and**

		spreadsheet to track timelines and submission of all forms. The OPO is in the second half of a year-long self assessment of its compliance with timely submission of forms, including feedback, DDR and PTR forms.
	C. Potential transplant recipient refusal codes	No response needed at this time.