



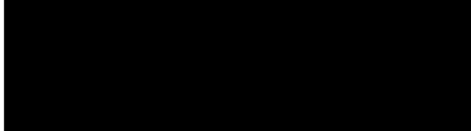
Since 1984 — sharing organs, sharing data, sharing life.



CONFIDENTIAL MEDICAL PEER REVIEW

April 8, 2011

Certified Mail/Return Receipt Requested



Alabama Organ Center

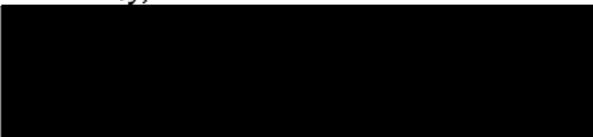


The UNOS Department of Evaluation and Quality conducted an onsite review at Alabama Organ Center on March 23-24, 2011.

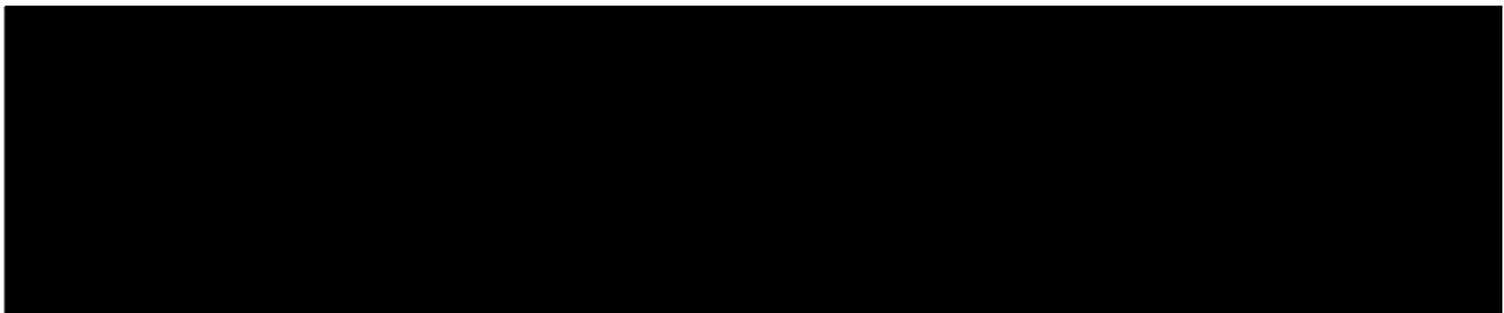
The site review included a review of 55 donor records. The review identified potential violations of OPTN Policies 2.2.4.1, 2.2.4.3, 2.5.7, 2.2.4, 2.2.5, 7.1.6, 7.1.7 and 7.5. The review also included an audit of the accuracy of information submitted on the Deceased Donor Registration (DDR) forms. The enclosed report includes the specific details and will require that you correct the identified errors on the DDR forms. Please provide a Corrective Action Plan (CAP) by April 22, 2011.

I appreciate the extensive preparation for the site visit put forth by the entire staff of Alabama Organ Center. If you have any questions, please contact me at [REDACTED]

Sincerely,



Site Surveyor
UNOS Department of Evaluation and Quality



[REDACTED]
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cc:

[REDACTED]
[REDACTED]
[REDACTED]
[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

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>

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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 UNetSM.

- 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 UNetSM

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
19 of 20 records accurate for serology results
20 of 20 records accurate for HLA typing

Donor ID #	UNet SM documentation	Donor Record documentation
██████████	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.

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:

- 2.0 Minimum Procurement Standards for an Organ Procurement Organization
- 3.2.4 Verification of the donor's ABO in UNetSM 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..."

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"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).**

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*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 2.0

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]

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.

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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		
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
	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
[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	Inotropic medications at cross clamp: Medication= Dopamine Dosage at time of cross clamp= 7mcg/kg/min Final dosage duration= 5.7 hours
	Vasopressin	Vasopressin is not an inotrope
[REDACTED]	Procurement and consent: Time of pronouncement of death= 11:10	Procurement and consent: Time of pronouncement of death= 11:05
	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:	Procurement and consent:

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	Time consent obtained for first organ= 01:30	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 *
	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.

<u>Validation of data submitted for Donor Summaries in attachment 3</u>		
10 donor summaries were reviewed 9 of 10 were accurate		
Donor ID	DonorNet® documentation	Donor record documentation
	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®.

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.

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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 UNetSM 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 UNetSM 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"***

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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		02/19/2010	55	N
2		02/26/2010	61	N
3		03/02/2010	61	N
4		03/04/2010	69	N
5		03/17/2010	58	N
6		04/30/2010	43	N
7		04/10/2010	19	N
8		04/17/2010	63	N
9		04/22/2010	40	N
10		05/11/2010	61	N
11		05/12/2010	63	N
12		05/18/2010	54	N
13		06/28/2010	27	N
14		06/30/2010	41	N
15		06/30/2010	57	N
16		06/14/2010	53	N
17		07/02/2010	3	N
18		07/15/2010	66	N
19		07/20/2010	50	N
20		08/26/2010	52	N
21		09/29/2010	54	N
22		09/13/2010	46	N
23		09/15/2010	59	N
24		09/18/2010	27	N

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"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"

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.

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

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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
			04/08/10	04/16/10	6	1
			05/25/10	06/07/10	8	3
			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.

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.
	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.
	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.
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 UNetSM.
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.
	C. Potential transplant recipient refusal codes	No response needed at this time.