

# **OPTN/UNOS Policy Notice**

## ***Improving the Efficiency of Organ Placement***

<b>Sponsoring Committee:</b>	<b>Organ Procurement Organization</b>
<b>Policy/Bylaws Affected:</b>	<b>1.2 Definitions, 2.2: OPO Responsibilities, 2.11: Required Deceased Donor Information, and 5.6: Receiving and Accepting Organ Offers</b>
<b>Public Comment:</b>	<b>July 31, 2017 – October 2, 2017</b>
<b>Effective Date:</b>	<b>March 1, 2018: Policies 2.2 (OPO Responsibilities), 2.11 (Required Deceased Donor 1 Information, and 2.12 (Requested Deceased Donor Information)</b> <b>Pending implementation and notice to OPTN members: Policies 1.2 (Definitions), 5.6.B (Time Limit for 5 Acceptance), and 5.6.C (Effect of Acceptance</b>

### **Problem Statement**

As the OPTN moves forward with proposals to increase the broader distribution of organs, members have expressed concerns that larger geographic districts could exacerbate any existing system inefficiencies. Inefficient organ placement can lead to decreased organ quality, logistical issues for OPOs and transplant hospitals, and have a negative impact on donor families. Identified inefficiencies include:

- Current time limits to access deceased donor information and either accept or refuse the organ offer are too long
- No current time limit for transplant hospitals to make a final decision on an organ offer made to the primary potential transplant recipient
- Transplant hospitals can currently accept an unlimited number of organ offers (for the same organ type) for one candidate. This can lead to late declines, which lead to logistical issues for OPOs.
- OPOs currently have up to 30 days to enter potential transplant recipient (PTR) information, which includes organ offer acceptances
- Policies 2.11 and 2.12 required updating, since the current information was not logical or clear

### **Summary of Changes**

- Reduces the current time limits for responding to organ offers to a combined one hour
- Establishes a new time limit for the primary transplant hospital to make a final decision on organ offers. The transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour. All other transplant hospitals that have entered a provisional yes must respond to the host OPO within 30 minutes of being notified that their candidate is now the primary potential transplant recipient.
- Establishes a limit of two organ offer acceptances for one candidate (for each organ type)
- Requires OPOs to report organ offer acceptances as soon as they are received

- Reorganizes *Policy 2.11: Required Deceased Donor Information*
- Eliminates *Policy 2.12: Requested Deceased Donor Information*. The OPO Committee is creating a guidance document that will replace this policy.

## What Members Need to Do

### Transplant Hospitals Must:

- Evaluate processes for receiving organ offers
- Make a final decision within one hour once the candidate becomes the primary potential transplant recipient
- Only accept two organ offers for one candidate (for the same organ type) at the same time

If you use third-party vendors to receive organ offers, they could be affected by the time limit reduction.

### OPOs Must:

- Indicate “organ placed” in DonorNet® in real time
- Review the changes to *Policy 2.11: Required Deceased Donor Information* in order to ensure timely and accurate reporting of donor information

## Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

## Policy 1.2 Definitions

### Organ offer acceptance

When the transplant hospital notifies the host OPO that they accept the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.

### Organ offer refusal

When the transplant hospital notifies the OPTN Contractor or the host OPO that they are declining the organ offer.

### Provisional yes

When the transplant hospital notifies the OPTN Contractor or the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.

## 2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. EnAssuring that the necessary tissue-typing material is procured, divided, and packaged.

9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information*, is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
134. ~~Ensuring that documentation for all of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs:~~
  - a. ABO source documentation
  - b. ABO subtype source documentation
  - c. Infectious disease results source documentation
  - d. Death pronouncement source documentation
  - e. Authorization for donation source documentation
  - f. ~~Human leukocyte antigen (HLA) type~~
  - g. ~~Donor evaluation and management~~
  - h. ~~Donor medical and behavioral history~~
  - i. ~~Organ intraoperative findings~~
145. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

## 2.11 Required Deceased Donor Information

The host OPO must ~~obtain report to the OPTN Contractor upon receipt~~ all of the following information for each potential deceased donor:

1. Age
2. Diagnosis (or cause of brain death)
- ~~3. Sex~~
3. Donor behavioral and social history
4. Donor management information
5. Donor medical history
6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
7. Ethnicity
8. Height
9. Organ anatomy and recovery information
11. Sex
12. All vital signs, including blood pressure, heart rate, and temperature
13. Weight

The potential transplant program team must have the opportunity to speak directly with responsible onsite OPO donor personnel to obtain current information about the deceased donor's physiology.

### **2.11.A Required Information for Deceased Kidney Donors**

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

- ~~1. Date of admission for the current hospitalization~~
- ~~2. Donor name~~
- ~~3. Donor ID~~
- ~~4. Ethnicity~~
- ~~5. Relevant past medical or social history~~
- ~~6. Current history of abdominal injuries and operations~~
- ~~7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria~~
- ~~8. Current medication and transfusion history~~
- ~~9.1. Anatomical description, including number of blood vessels, ureters, and approximate length of each~~
2. Biopsy results, if performed
- ~~10. 3. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers~~
- ~~11. Indications of sepsis~~
- ~~12. 4. Injuries to or abnormalities of blood vessels, ureters, or kidney~~
5. Kidney perfusion information, if performed
- ~~13. Assurance that final blood and urine cultures are pending~~
- ~~14. Final urinalysis~~
- ~~15. Final blood urea nitrogen (BUN) and creatinine~~
- ~~16. Recovery blood pressure and urine output information~~
- ~~17. Recovery medications~~
- ~~18. Type of recovery procedure, flush solution and method, and flush storage solution~~
- ~~19. Warm ischemia time and organ flush characteristics~~

### **2.11.B Required Information for Deceased Liver Donors**

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

- ~~1. Donor name~~
- ~~2. Donor ID~~
- ~~3. Ethnicity~~
- ~~4. Height~~
- ~~5. Weight~~
- ~~6. Vital signs, including blood pressure, heart rate and temperature~~
- ~~7. Social history, including drug use~~
- ~~8. History of treatment in hospital including current medications, vasopressors, and hydration~~
- ~~9. Current history of hypotensive episodes, urine output, and oliguria~~
- ~~10. Indications of sepsis~~
- ~~11. Aspartate aminotransferase (AST)~~
- ~~12. Bilirubin (direct)~~
1. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program
- ~~13. 2. Other laboratory tests within the past 12 hours of the offer including:~~
  - ~~a. Alanine aminotransferase (AST)/aspartate aminotransferase (ALT/AST)~~

- b. Alkaline phosphatase
- c. Total and direct bilirubin
- d. ~~Creatinine~~
- e. ~~Hemoglobin (hgb) and hemocrit (het)~~
- fd. International normalized ratio (INR) or Prothrombin (PT) if INR is not available, ~~and~~
- e. Partial thromboplastin time (PTT)
- g. ~~White blood cell count (WBC)~~
- 3. Pre-procurement biopsy results, if performed
- 4. Pre-procurement CT imaging results, if performed
- 14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program

If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.

### **2.11.C Required Information for Deceased Heart Donors**

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

- 1. ~~Height~~
- 2. ~~Weight~~
- 3. ~~Vital signs, including blood pressure, heart rate, and temperature~~
- 4. ~~History of treatment in hospital including vasopressors and hydration~~
- 5. ~~Cardiopulmonary, social, and drug activity histories~~
- 6. ~~Details of any documented cardiac arrest or hypotensive episodes~~
- 7-1. 12-lead interpreted electrocardiogram interpretation, if available
- 8-2. Arterial blood gas results and ventilator settings
- 9-3. Cardiology consult, if performed or echocardiogram, if the hospital has the facilities
- 4. Echocardiogram
- 10-5. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance

For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

### **2.11.D Required Information for Deceased Lung Donors**

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

- 1. ~~Height~~
- 2. ~~Weight~~
- 3. ~~Vital signs, including blood pressure, heart rate, and temperature~~
- 4. ~~History of medical treatment in hospital including vasopressors and hydration~~

- ~~5. Smoking history~~
- ~~6. Cardiopulmonary, social, and drug activity histories~~
- ~~7.1. Arterial blood gases and ventilator settings on 5 cm/H<sub>2</sub>O/PEEP including PO<sub>2</sub>/FI<sub>2</sub> ratio and preferably 100% FI<sub>2</sub>, within 2 hours prior to the offer~~
- ~~8.2. Bronchoscopy results, if performed~~
- ~~9.3. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer~~
- ~~4. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance~~
- ~~10. Details of any documented cardiac arrest or hypotensive episodes~~
- ~~11.5. Sputum gram stain, with description of sputum~~
- ~~12. Electrocardiogram~~
- ~~13. Echocardiogram, if the OPO has the facilities~~
- ~~14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance~~

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.

~~For lung deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.~~

~~The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.~~

## **2.11.E Required Information for Deceased Pancreas Donors**

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

- ~~1. Donor name~~
- ~~2. Donor ID~~
- ~~3. Ethnicity~~
- ~~4. Weight~~
- ~~5. Date of admission for the current hospitalization~~
- ~~6. Alcohol use (if known)~~
- ~~7. Current history of abdominal injuries and operations including pancreatic trauma~~
- ~~8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria~~
- ~~9. Current medication and transfusion history~~
- ~~10. Pertinent past medical or social history including pancreatitis~~
- ~~11. 1. Familial Family history of diabetes (including Type 1 and Type 2)~~
- ~~2. Hemoglobin A1C, if performed~~
- ~~3. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers~~
- ~~12. 4. Insulin protocol~~
- ~~13. Indications of sepsis~~
- ~~14. 5. Serum amylase~~

15. ~~6. Serum lipase~~
16. ~~HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers~~

## **2.12 Requested Deceased Donor Information**

### **2.12.A — Kidney**

~~With each kidney offer, the host OPO should provide the receiving transplant program with the following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:~~

1. ~~Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)~~
2. ~~A sample that captures a minimum of 25 glomeruli~~
3. ~~A frozen or fixed section slide, or the biopsy material, may accompany the kidney.~~

### **2.12.B — Heart**

~~With each heart offer, the host OPO should provide all of the following information to the receiving transplant hospital:~~

1. ~~Coronary angiography (for male donors over 40 years old or female donors over 45 years old)~~
2. ~~Central venous pressure (CVP) or Swan Ganz instrumentation~~
3. ~~Cardiology consult~~
4. ~~Cardiac enzymes, including creatinine phosphokinase (CPK) isoenzymes~~

~~A transplant hospital may request a heart catheterization of the deceased donor where the donor's medical or social history reveals at least one of the following past medical histories:~~

- ~~Male over 40 years old or female over 45 years old~~
- ~~Segmental wall motion abnormality on echo~~
- ~~Troponin elevation~~
- ~~History of chest pain~~
- ~~Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction~~
- ~~History of two or more of the following:~~
  - ~~Cocaine or amphetamine use~~
  - ~~Diabetes~~
  - ~~Hyperlipidemia~~
  - ~~Hypertension~~
  - ~~Intra-cerebral bleeding~~
  - ~~Significant smoking~~
  - ~~Strong family history of coronary artery disease~~

### **2.12.C — Lung**

~~The host OPO should provide all of the following information to the receiving transplant hospital:~~

1. ~~Measurement of chest circumference at the level of nipples~~
2. ~~Measurement by chest x ray vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm~~
3. ~~Mycology sputum smear~~

4. ~~Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant hospital~~

## 2.132 Post Procurement Follow Up and Reporting

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

### 5.6.B Time Limit for Review and Acceptance of Organ Offers

~~A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.~~

~~Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to *Policy 2.3: Evaluating and Screening Potential Deceased Donors*. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.~~

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to VCA transplants.

### 5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have two organ offer acceptances for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN Contractor.

### 5.6.CD Effect of Acceptance

When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.

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