UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

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

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4817
www.unos.org

IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of actions taken at OPTN/UNOS Board of Directors Meeting: June 24-25, 2013

Date: July 25, 2013

The attached report summarizes changes to OPTN Policy and Bylaws approved by the OPTN/UNOS Board of Directors. This policy notice provides the specific Policy and Bylaws language changes and the corresponding implementation dates. When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the changes approved at the June 2013 Board of Directors meeting reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on "News," and then select "View all Policy Notices").

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, has also been updated to reflect the changes resulting from the these meeting. It can also be found at optn.transplant.hrsa.gov (click on "Policy Management," and then select "Evaluation Plan").

Thank you for your careful review of this policy notice. If you have any questions about a particular Board of Directors' action, please contact your regional administrator at (804) 782-4800.

Table of Contents

Substantial Revision of the National Kidney Allocation System

Sponsoring Committee: Kidney Transplantation Committee

Policies Affected:

- 3.5 (Allocation of Deceased Kidneys)
- 3.1.13 (Definition of Directed Donation)
- 3.2.4.2 (Waiting Time Reinstatement for Kidney Recipients)
- 3.3.5 (Transplant Recipient Backups for Organ Offers)
- 3.4.2 (Time Limit for Acceptance)
- 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time)
- 3.8.3.2 (Blood Type O Kidney-Pancreas Allocation)
- 3.8.3.5 (Organ Offer Limits)
- 3.8.4.1 (CPRA)
- 3.8.4.3 (Waiting Time)
- 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)
- 6.4.1.1 (Requirements for Importing Deceased Donor Organs through a Formal Agreement)
- 9.6.8
- 12.5.6 (Placement of Non-directed Living Donor Organs)
- 12.9.4 (Exception for Prior Living Donor Organs)

Distributed for Public Comment: September 2012

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement
The current kidney allocation system does not match candidate longevity with kidney longevity. This results in an inefficient use of donor kidneys and unnecessarily high re-transplant rates. Additionally, there is a higher than necessary discard rate of kidneys that could otherwise benefit candidates on the waiting list. Variability in access to transplantation by candidate blood type and geographic location also exists.

Changes
The kidney allocation system will include the following elements: • Kidney Donor Profile Index (KDPI) will replace standard/expanded criteria donor (SCD/ECD) designations. • Candidates will receive credit for time spent on dialysis prior to listing. • Candidates with CPRA scores of 20% or above will receive points based on a sliding scale. • Candidates with blood type B who meet clinical criteria defined by their transplant programs will be eligible to accept kidneys from donors with blood type A, non-A_1 and blood type AB, non-A_1B. • The 20% of adult candidates with the longest estimated post-transplant survival (EPTS) will receive priority for kidneys from donors with KDPI scores in the top 20%. • Priority for pediatric candidates will be based on donor KDPI instead of donor age.

- The kidney payback system will be eliminated.
- Variances to the kidney allocation system that were not incorporated into national policy will be eliminated.

Member Actions

Implementation of these changes will take place in two phases:

- Phase 1:
  - Transplant programs will begin updating essential data elements for all candidates. These data elements include dialysis start date, number of prior solid organ transplants, and diabetes status. Tools and support will be available to assist with these data updates.
  - Transplant programs should develop written policies for blood type B candidate eligibility for organs from blood type A, non-A_1 and blood type AB, non-A_1B donors.
  - Transplant programs should revise consent forms for ECD kidneys to align with new classifications of KDPI >85%.
- Phase 2:
  - Allocation will begin according to the new policies.
  - The kidney payback system will be eliminated.
  - Kidney allocation variances will be eliminated.

UNOS will alert members before each phase is implemented. UNOS will also provide training on the new kidney allocation system for patients and transplant professionals.

Click here to view the modified policy language

OPTN/UNOS Finance Committee Composition Change

Sponsoring Committee: Executive Committee

Bylaws Affected: Bylaws Article VII (Permanent Standing Committees); Article 7.6 (Conflicts of Interest); and newly approved Article 7.6 (Finance Committee)

Distributed for Public Comment: September 2012

Amended After Public Comment: No

Effective Date: June 25, 2013

Problem Statement
For most organizations, financial governance includes a finance committee that resides at the board level. The OPTN/UNOS Finance Committee, however, has been a permanent standing committee with regional and at-large appointments, and is separate from the OPTN/UNOS Board of Directors.

Changes
These Bylaws changes will result in the Finance Committee being composed solely of members of the Board. The President may appoint additional non-voting advisors to the Finance Committee, subject to approval by the Board.

Member Actions
These modifications pertain to governance of the OPTN. No member actions are required.

Click here to view the modified bylaws language.

Changes to the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

Sponsoring Committee: Membership and Professional Standards Committee

Bylaws Affected: Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs), Section D.9 (Review of Transplant Program Functional Inactivity) and Section D.10 (Additional Transplant Program Requirements); Appendix K (Transplant Program Inactivity, Withdrawal, and Termination), Section K.1 (Transplant Program Inactivity)

Distributed for Public Comment: September 2012

Amended After Public Comment: Yes

Effective Date: Appendix D, Sections D.9 and D.10 will be effective January 1, 2014; Appendix K, Section K.1 will be effective September 1, 2013

Problem Statement
Current OPTN/UNOS Bylaws do not clearly outline the actions a member must take when it becomes functionally inactive or if a program voluntarily ceases performing a specific type of transplant.

Changes
These Bylaws changes clarify functional inactivity notification requirements. The modified Bylaws indicate specifically how and when transplant program staff must notify patients whenever they inactivate their waiting list in UNet℠. The modifications also specify how transplant program staff must notify patients if the transplant program voluntarily ceases performing a specific type of transplant. Modifications to Appendix D, Sections D.9 and D.10 include: • Moving waiting list inactivity requirements from Section D.9 to Section D.10 • Changing cohort from a rolling 365-day period to a calendar year • Defining patient notification content and delivery requirements for transplant programs that meet waiting list inactivation thresholds • Changing monitoring requirements from peer review monitoring of members that meet thresholds to DEQ staff annual review Modifications to Appendix K, Section K.1 include: • Defining transplant program component cessation and affected patients that must be notified, depending on the ceased component

Member Actions
Members should be aware of the patient notification requirements for each situation addressed by these Bylaws, and, when applicable, comply with notification content and delivery requirements.

Click here to view the modified bylaws language.

Elimination of OPTN/UNOS Bylaws Authorizing the Combined Heart-Lung Transplant Program Designation

Sponsoring Committees: Membership and Professional Standards Committee and Thoracic Organ Transplantation Committee

Bylaws Affected: Appendix J (Membership and Personnel Requirements for Joint Heart and Lung Programs)

Distributed for Public Comment: September 2012

Amended After Public Comment: No

Effective Date: September 1, 2013

Problem Statement
With the exception of heart-lung transplantation, the OPTN authorizes all combined simultaneous organ transplants if the member hospital has transplant program designation and approval to perform each respective organ transplant. In addition to being inconsistent, this has also created programming issues.

Changes
OPTN Bylaws Appendix J (Membership and Personnel Requirements for Joint Heart and Lung Programs) will be eliminated. With this change the Bylaws will authorize only single organ transplant program designations and approvals. Transplant hospitals with designation and approval to perform heart transplants and designation and approval to perform lung transplants may perform simultaneous heart-lung transplants.

Member Actions
If transplant hospitals currently hold approved heart-lung transplant program status, no action is required. UNOS will notify these hospitals that this program status is being eliminated. Patients currently listed for a heart-lung transplant will not be affected and do not need to be notified of this change. Please note that programming is required to remove the heart-lung transplant program status in the membership database. This will be performed at a later date (to be determined) but is not required to implement this Bylaws change.

Click here to view the modified bylaws language.

Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions

Sponsoring Committee: Organ Procurement Organization (OPO) Committee

Policies Affected: Policies 7.1.6 (Eligible Death Definition) and 7.1.7 (Imminent Neurological Death)

Distributed for Public Comment: September 2012

Amended After Public Comment: Yes

Effective Date: December 1, 2013

Problem Statement
OPOs inconsistently report imminent and eligible neurological deaths because they interpret multi-system organ failure differently and because brain death laws vary from state to state. This inconsistent reporting affects the accuracy and usefulness of data analyses used to measure OPO performance and facilitate process improvement.

Changes
The multi-system organ failure exclusion has been removed from the eligible death definition and replaced by "rule out" criteria for each individual organ system. Additionally, the imminent neurological death policy has plain language revisions and formatting changes to make it easier to understand.

Member Actions
OPOs must review these policy changes and, upon implementation, apply the new definitions when reporting imminent and eligible death data on the Death Notification Registration form. Please note that the imminent and eligible definitions are "reporting" definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to exclude potential organ donors and do not prevent an OPO from pursuing a donor candidate that is not classified as an eligible death. As a reminder, Centers for Medicare & Medicaid Services (CMS) has its own definitions for reporting imminent and eligible deaths. Please reference CMS guidelines for its imminent and eligible death reporting definitions.

Click here to view the modified policy language.

Requirement to Report Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion

Sponsoring Committee: Pancreas Transplantation Committee

Policies/Bylaws Affected: Policies 3.2.1.8.1 (Permissible Modifications), Policy 3.8 (Pancreas Allocation Policy), 3.8.7.2 (Accrual of Waiting Time), 3.8.7.4 (Process for Re-Allocating Islets.), 3.8.7.5 (Removal from the Pancreas Islet Waiting List), and Bylaws Article 1 (Membership), Section 1.2.D (Registration Fees), and Appendix G (Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs)

Distributed for Public Comment: September 2012

Amended After Public Comment: Yes

Effective Date: September 1, 2013

Problem Statement
Currently, islet transplant programs are not required to report every islet infusion to UNOS. Therefore, it is possible that UNOS may be unaware which islet recipients have received infusions which could have patient safety or disease transmission implications.

Changes
These changes require accurate and timely reporting of every islet infusion. The changes also update language to reflect the current practice for reporting islet infusions and outcomes. Specific changes include: • Requiring islet programs to report each islet infusion to UNOS within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions. • Removing outdated requirements in the Bylaws for submitting islet logs. • Adding language to reflect current programming for when an additional registration fee is generated after a transplant program removes an islet candidate from the waiting list for transplant and immediately re-registers that candidate for another infusion.

Member Actions
Transplant programs must report each islet infusion to UNOS within 24 hours of the infusion. To do this, islet transplant programs must remove islet recipients from the waiting list within 24 hours of each islet infusion instead of within 24 hours of the recipient's third islet infusion. Policy 3.2.8 (Patient Notification) requires that transplant programs notify patients in writing within 10 business days of the patient's waiting list registration date. Transplant programs should review their patient notification protocol to make sure it is addressing cases when an islet recipient receives an islet transplant and is immediately re-registered for another infusion. Islet programs will no longer be required to submit cumulative islet logs that report each islet infusion and outcome.

Click here to view the modified policy and bylaws language.

Affected Policy Language:

Policy 3.5: Allocation of Kidneys

Introduction

This Policy contains requirements for the allocation of kidneys and certain rules regarding kidney candidate registrations.

Policy Statement

3.5.1 Calculated Panel Reactive Antibody

Calculated Panel Reactive Antibody (CPRA) is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. In order to list an unacceptable antigen, the Transplant Hospital must do at least one of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplantation. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, as well as considerations for unexpected positive crossmatches and other circumstances.
- Base unacceptable antigens on laboratory detection of HLA specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant Hospitals may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be calculated automatically when a Transplant Hospital reports unacceptable antigens to the OPTN Contractor. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

3.5.2 Exceptions

Prior to receiving an organ offer from a donor in the same local unit, a candidate's physician may use his medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the local unit, then the candidate's physician must receive agreement from the other kidney transplant programs in the local unit and must maintain documentation of this decision in the candidate's medical record.

3.5.3 Points

Candidates receive points according to Table 3.5-1: *Kidney Points*.

Table 3.5-1: Kidney Points

If the candidate is…	And the following allocation sequence is used...	Then the candidate receives this many points…
Listed for transplant and meets the qualifying criteria described in Policy 3.5.4 *Waiting Time*	3.5.6.1, 3.5.6.2, 3.5.6.3, or 3.5.6.4	1/365 points for each day since the qualifying criteria in Policy 3.5.4 *Waiting Time*

If the candidate is…	And the following allocation sequence is used...	Then the candidate receives this many points…
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	3.5.6.1 or 3.5.6.2	1 point
A prior living donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	4 points
Sensitized (CPRA at least 20%)	3.5.6.1, 3.5.6.2, or 3.5.6.3	*See* Table 3.5-2: *Points for CPRA*
Sharing a single HLA-DR mismatch with the donor*	3.5.6.1, 3.5.6.2, or 3.5.6.3	1 point
Sharing a zero HLA-DR mismatch with the donor*	3.5.6.1, 3.5.6.2, or 3.5.6.3	2 points

**Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.*

Table 3.5-2: Points for CPRA

If the candidate's CPRA score is…	Then the candidate receives this many points…
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

3.5.4 Waiting Time

3.5.4.1 Waiting Time for Candidates Listed After Age 18

If a candidate is 18 years of age or older on the date he is registered for a kidney, then the candidate's waiting time is based on the earlier of the following:

1. The candidate's registration date with a measured or calculated creatinine clearance or glomerular filtration rate (GFR), less than or equal to 20 ml/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR becomes less than or equal to 20 ml/min.
3. The date that the candidate began dialysis that is regularly administered to an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

With the exception of candidates who experience immediate and permanent non-function of a transplanted kidney, only dates after the most recent kidney transplant apply for #1-3 above. Refer to Policy 3.2.4.2 *Waiting Time Reinstatement for Kidney Recipients* to determine eligibility for waiting time reinstatement.

3.5.4.2 Waiting Time for Candidates Listed Prior to Age 18

If a candidate is younger than 18 years of age on the date he is registered for a kidney, the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered regardless of clinical criteria.
2. The date that the candidate began dialysis that is regularly administered to an ESRD patient in a hospital based, independent non-hospital based or home setting.

With the exception of candidates who experience immediate and permanent non-function of a transplanted kidney, only dates after the most recent kidney transplant apply for #1-2 above. Refer to Policy 3.2.4.2 *Waiting Time Reinstatement for Kidney Recipients* to determine eligibility for waiting time reinstatement.

3.5.5 Classification Notes

3.5.5.1 Candidate Classifications

Each candidate on the kidney waiting list after turning 18 years old receives an Estimated Post Transplant Survival (EPTS) score. EPTS is based on *all* of the following factors:

1. candidate time on dialysis
2. whether or not the candidate has a current diagnosis of diabetes
3. whether or not the candidate has had any prior solid organ transplant
4. candidate age

With the exception of candidates who experience immediate and permanent non-function of a transplanted kidney, only time on dialysis after the most recent kidney transplant applies for #1 above. Refer to Policy 3.2.4.2 *Waiting Time Reinstatement for Kidney Recipients* to determine whether a candidate meets this criteria.

Each candidate's EPTS score is calculated at time of registration. The OPTN Contractor will update EPTS scores as follows:

1. all candidate EPTS scores will be updated once each day

2. a candidate's EPTS score will be updated anytime the transplant hospital reports changes to any EPTS factor for a candidate.

A candidate's raw EPTS score is equal to:

0.047 * MAX(Age - 25, 0) +
-0.015 * Diabetes * MAX(Age - 25, 0) +
0.398 * Prior Solid Organ Transplant +
-0.237 * Diabetes * Prior Solid Organ Transplant +
0.315 * log(Years on Dialysis + 1) +
-0.099 * Diabetes * log(Years on Dialysis + 1) +
0.130 * (Years on Dialysis = 0) +
-0.348 * Diabetes * (Years on Dialysis = 0) +
1.262 * Diabetes

The following factors in the EPTS calculation are binary indicators: diabetes, prior solid organ transplant, years on dialysis=0. If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate's age and years on dialysis.

The EPTS mapping table, made available by the OPTN contractor, is used to convert a candidate's raw EPTS score into an EPTS score. A candidate's EPTS score represents the percentage of kidney candidates in the nation with a higher expected post-transplant survival time. The percentage is rounded to the nearest integer.

The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

3.5.5.2 Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The donor characteristics used to calculate KDRI are provided in Table 3.5-3: *KDRI* **Factors**.

Table 3.5-3: KDRI Factors

This donor characteristic…	Applies to…	KDRI score component
Age (integer years)	All donors	0.0128*(age-40)
	Donors with age < 18	-0.0194*(age-18)
	Donors with age > 50	0.0107*(age-50)
Ethnicity	African American donors	0.1790
Creatinine (mg/dl)	All donors	0.2200*(creatinine - 1)
	Donors with creatinine > 1.5	-0.2090*(creatinine - 1.5)
History of Hypertension	Hypertensive donors	0.1260
History of Diabetes	Diabetic donors	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881

This donor	Applies to…	KDRI score
Height (cm)	All donors	-0.0464*(height -170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0199*(weight - 80) / 5
Donor type	DCD donors	0.1330
HCV status	HCV positive donors	0.2400

To calculate KDRI, sum each of the applicable KDRI score components in Table 3.5-3, and then apply the antilog (base e) function to this sum. Divide the KDRI by the median KDRI value of the most recent donor reference population, and determine the KDPI using the KDRI-to-KDPI mapping table made available by the OPTN Contractor.
The KDPI used for allocation is based on the most recent values of donor characteristics (e.g., the latest serum creatinine) reported to the OPTN Contractor prior to running a match.
The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.
The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI. This percentage is rounded to the nearest integer.

3.5.5.3 Consent for Kidneys Based on KDPI Greater than 85%
Prior to receiving an offer for a kidney with a KDPI score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category.

3.5.5.4 Sorting Within Each Classification
Within each classification, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

3.5.5.5 Blood Type Permissibility
Transplants are restricted by blood type in certain circumstances.

- Blood type O kidneys must be transplanted only into blood group O candidates.
    - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
- Blood type B kidneys must be transplanted only into blood type B candidates
    - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
- Blood type non-A_1 (i.e., A_2) and non-A_1B (i.e., A_2B) kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria:
    - The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a non-A_1 or non-A_1B blood type kidney

- The transplant program establishes a written policy regarding its program's titer threshold for transplanting non-A_1 and non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

Kidney candidate and donor blood types are matched according to *Table 3.5-4: Blood Typing for Kidney* **Allocation**. Fields with a "●" indicate identical blood type matches. Fields with a "◑" indicate non-identical blood type matches. Fields with a "○" indicate incompatible (and therefore, impermissible) blood type matches. Fields with a "*" indicate permissible blood type matches only if the candidate is 0 ABDR mismatch, otherwise the match is not permissible. Fields with a "**" indicate permissible blood type matches only if the candidate is non-A_1/non-A_1B eligible, otherwise the match is not permissible.

Table 3.5-4: Blood Typing for Kidney Allocation

Donor's Blood Type	Candidate is O	Candidate is A	Candidate is B	Candidate is AB
O	●	◑*	◑*	◑*
A	○	●	○	◑
A, Non-A_1	○	●	◑**	◑
B	○	○	●	◑*
AB	○	○	○	●
AB, Non-A_1B	○	○	◑**	●

3.5.5.6 Prior Living Organ Donors

A candidate will be classified as a prior living donor and receive priority for each kidney registration if *all* of the following conditions are met:

1. The candidate donated at least one of the following for transplantation within the United States or its territories:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate's physician reports all of the following information to the OPTN Contractor:
   - The name of the recipient or intended recipient of the donated organ or organ segment
   - The recipient's or intended recipient's Transplant Hospital
   - The date the donated organ was procured

3.5.5.7 Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in allocation classifications 1-10 in allocation sequences 3.5.6, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and

sign a written approval of the unacceptable antigens listed for the candidate. The Transplant Hospital must document this approval in the candidate's medical record.

3.5.6 Kidney Allocation Classifications and Rankings

3.5.6.1 Allocation of Kidneys from Donors with KDPI Scores Less than or Equal to 20%

Kidneys from donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates in the following order:

Table 3.5-5: Allocation of Kidneys from Donors with KDPI less than or equal to 20%

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
1	OPO's local unit	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
2	OPO's local unit	CPRA equal to 100%, blood type identical or permissible	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
4	OPO's region	CPRA equal to 100%, blood type identical or permissible	Any
5	Nation	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Any
6	Nation	CPRA equal to 100%, blood type identical or permissible	Any
7	OPO's local unit	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
8	OPO's local unit	CPRA equal to 99%, blood type identical or permissible	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
10	OPO's region	CPRA equal to 99%, blood type identical or permissible	Any
11	OPO's local unit	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	Any
12	OPO's local unit	CPRA equal to 98%, blood type identical or permissible	Any
13	OPO's local unit	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, and blood type identical	Any
14	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		run, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	
15	Nation	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any
19	Nation	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's local unit	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, and blood type B	O
23	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, Top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type	O

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
		B	
25	OPO's region	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
26	Nation	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
27	OPO's region	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
28	Nation	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
29	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at the time of the match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, Top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's local unit	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, and blood type permissible	Any
32	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
35	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		than 79%, and blood type permissible	
36	OPO's region	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
37	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, Top 20% EPTS or less than 18 years old at the time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's local unit	Prior living donor, blood type permissible or identical	Any
41	OPO's local unit	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's local unit	Top 20% EPTS, blood type B	A2 or A2B
43	OPO's local unit	Top 20% EPTS, blood type permissible or identical	Any
44	OPO's local unit	0-ABDR mismatch, EPTS greater than 20%, blood type identical	Any
45	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
46	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
47	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
48	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		21% but no greater than 79%, and blood type identical	
49	OPO's local unit	0-ABDR mismatch, EPTS greater than 20%, and blood type B	O
50	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
51	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
52	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
53	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
54	OPO's local unit	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	Any
55	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
57	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
58	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
59	OPO's local unit	EPTS greater than 20%, blood type B	A2 or A2B
60	OPO's local unit	All remaining candidates, blood type permissible or identical	Any
61	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
62	OPO's region	Top 20% EPTS, blood type B	A2 or A2B
63	OPO's region	Top 20% EPTS, blood type permissible or identical	Any
64	OPO's region	EPTS greater than 20%, blood type B	A2 or A2B
65	OPO's region	All remaining candidates, blood type permissible or identical	Any
66	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
67	Nation	Top 20% EPTS, blood type B	A2 or A2B
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.2 Allocation of Kidneys from Donors with KDPI Scores Greater than 20% but Less than 35%

Kidneys from donors with KDPI scores greater than 20% but less than 35% are allocated to candidates in the following order:

Table 3.5-6: Allocation of Kidneys from Donors with KDPI Scores Greater than 20% but Less than 35%

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
1	OPO's local unit	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's local unit	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's local unit	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's local unit	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's local unit	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's local unit	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's local unit	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
22	OPO's local unit	0-ABDR mismatch, blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's local unit	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's local unit	Prior living donor, blood type permissible or identical	Any
41	OPO's local unit	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's local unit	Blood type B	A2 or A2B
43	OPO's local unit	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
45	OPO's region	Blood type B	A2 or A2B
46	OPO's region	All remaining candidates, blood type permissible or identical	Any
47	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
48	Nation	Blood type B	A2 or A2B
49	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.3 Allocation of Kidneys from Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates in the following order:

Table 3.5-7: Allocation of Kidneys from Donors with KDPI Greater than or equal to 35% and Less than or equal to 85%

Classification	Candidates that are within the…	And are…	And the donor is this blood type
1	OPO's local unit	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type
		identical	
2	OPO's local unit	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's local unit	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's local unit	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's local unit	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's local unit	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's local unit	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match,	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type
		and blood type identical	
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's local unit	0-ABDR mismatch, and blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's local unit	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's local unit	Prior living donor, blood type permissible or identical	Any
41	OPO's local unit	Blood type B	A2 or A2B
42	OPO's local unit	All remaining candidates, blood type permissible or identical	Any
43	OPO's region	Blood type B	A2 or A2B
44	OPO's region	All remaining candidates, blood type permissible or identical	Any
45	Nation	Blood type B	A2 or A2B
46	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.4 Allocation of Kidneys from Donors with KDPI Scores Greater than 85%
With the exception of 0-ABDR mismatches, kidneys from donors with KDPI scores greater than 85% will be allocated to adult candidates only.

Kidneys from donors with KDPI scores greater than 85% are allocated to candidates in the following order:

Table 3.5-8: Allocation of Kidneys from Donors with KDPI Scores Greater than 85%

Classification	Candidates that are within the…	And are…	And the donor is this blood type…
1	OPO's local unit	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's local unit	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's local unit	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's local unit	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's local unit	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's local unit	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's local unit	0-ABDR mismatch, blood type permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's local unit	0-ABDR mismatch, blood type B	O
19	OPO's region	0-ABDR mismatch, CPRA greater than	O

Classification	Candidates that are within the…	And are…	And the donor is this blood type…
		or equal to 80% but no greater than 100%, and blood type B	
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
23	OPO's local unit	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's region	Blood type B	A2 or A2B
29	OPO's region	All remaining candidates, blood type permissible or identical	Any
30	Nation	Blood type B	A2 or A2B
31	Nation	All remaining candidates, blood type permissible or identical	any

3.5.6.5 Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in Policies 3.5.6.1 *Allocation of Kidneys from Donors with KDPI Scores Less than or Equal to* 20%- 3.5.6.4 *Allocation of Kidneys from Donors with KDPI Scores Greater than 85%* before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the donor meets *at least two* of the following criteria:

- Age is greater than 60 years
- Estimated creatinine clearance is less than 65 ml/min based upon serum creatinine at admission
- Rising serum creatinine (greater than 2.5 mg/dl) at time of organ recovery

- History of longstanding hypertension or diabetes mellitus
- Glomerulosclerosis greater than 15% and less than 50%.

3.5.7 Administrative Rules

3.5.7.1 Mandatory Sharing

Kidneys shared as 0-ABDR mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1-10 in allocation sequences 3.5.6.1 through 3.5.6.4 must be offered within the following time limits:

Table 3.5-9: Organ Offer Limit

If the donor is…	The OPO must make at least this many offers …	Then the OPO must offer the kidneys within this many hours of procurement…
KDPI ≤ 85%	10	8 hours
KDPI >85%	5	3 hours

3.5.7.2 Choice of Right versus Left Donor Kidney

If both kidneys from a donor are transplantable, the Transplant Hospital that is offered a kidney for a candidate may select which of the two kidneys it will receive. The Transplant Hospital which received the offer for the candidate with higher priority on the waiting list will have selection preference.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1-10 in allocation sequences 3.5.6.1 through 3.5.6.4, or to a combined kidney and non-renal organ candidate, the Host OPO determines whether to offer the left or the right kidney.

3.5.7.3 National Kidney Offers

With the exception of 0-ABDR mismatched kidneys and kidneys shared nationally for 100% CPRA candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact the OPTN Contractor to assist with national placement.

The importing OPO must select any alternate candidates according to Policy 3.5.6 in the event that the kidney cannot be transplanted into the original intended candidate.

3.5.7.4 Minimum Information/Tissue for Kidney Offer

The Host OPO must provide the following information to the potential recipient center with each kidney offer:

i. Donor name and Donor I.D. number, age, sex, and race;
ii. Date of admission for the current hospitalization;
iii. Diagnosis;
iv. Blood type;
v. ABO subtype when used for allocation;
vi. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A;
vii. Current history of abdominal injuries and operations;
viii. Pertinent past medical or social history;

ix. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
x. Final urinalysis;
xi. Final BUN and creatinine;
xii. Indications of sepsis;
xiii. Assurance that final blood and urine cultures are pending;
xiv. Serologies as indicated in 2.2.4.1 qualified specimens preferred as noted in Policy 2.2.3.1);
xv. Current medication and transfusion history;
xvi. Recovery blood pressure and urine output information;
xvii. Recovery medications;
xviii. Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
xix. Description of typing material available, including, as a minimum for each kidney:
    - One 7 to 10ml. clot (red topped) tube for ABO Verification, plus
    - 2 ACD (yellow top) tubes
    - 3 to 5 lymph nodes
    - One 2 X 4 cm wedge of spleen in culture medium, if available
xx. Warm ischemia time and organ flush characteristics; and
xxi. Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood

3.5.7.5 Computer Entry

Information regarding each and every deceased kidney donor must be entered into UNetSM prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

3.5.7.6 Kidney/Non-Renal Exception

In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates.

3.5.7.7 Allocation of Deceased Kidneys with Discrepant HLA Typings

Allocation of deceased kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the donor, the kidney may be allocated in accordance with the original HLA typing, or the recipient center may reallocate the kidney locally, according to Policy 3.5.

3.5.7.8 Prospective Crossmatching

A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch

may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

3.5.8 Variances

Reserved

3.5 ALLOCATION OF DECEASED KIDNEYS. Deceased kidneys must be allocated according to the following policies. The final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of the candidate. This allows physicians and surgeons to exercise their medical judgment regarding the suitability of the organ being offered for a specific candidate; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If an organ is declined for a candidate, a notation of the reason for that decision must be made on the appropriate form and submitted promptly.

3.5.1 Definition of Expanded Criteria Donor and Standard Donor. For purposes of Policy 3.5 (Allocation of Deceased Kidneys), expanded criteria donors are defined by an "X" in the decision matrix shown below indicating relative risk of graft failure for donors older than 10 years of age > 1.7, based upon the following factors: age, creatinine, CVA, and hypertension. Standard donors are all other donors. Unless specified as an expanded criteria donor or standard donor, the term donor(s) means all donors, expanded and standard. For purposes of distinguishing expanded criteria donors from standard donors, the most recent creatinine at the time of kidney placement shall be used.

Candidates who agree to receive expanded criteria donor kidneys shall be eligible also to receive standard donor kidneys according to the policies described below for allocating standard donor kidneys. The program shall obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation.

Donor Condition	**Donor Age Categories**				
	< 10	**10 – 39**	**40 – 49**	**50 – 59**	**≥ 60**
CVA + HTN + Creat > 1.5				**X**	**X**
CVA + HTN				**X**	**X**
CVA + Creat > 1.5				**X**	**X**
HTN + Creat > 1.5				**X**	**X**
CVA					**X**
HTN					**X**
Creatinine > 1.5					**X**
None of the above					**X**

X=Expanded Criteria Donor

CVA=CVA was cause of death

HTN=history of hypertension at any time

Creat > 1.5 = creatinine > 1.5 mg/dl

3.5.2 ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients. Blood type O kidneys must be transplanted only into blood type O candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O candidates and kidneys from a blood type B donor are to be allocated only to blood type B candidates, with the exception for zero antigen mismatched candidates noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.

3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1,A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNet^{SM} prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[4] if there is a pediatric candidate or a sensitized

~~adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1], if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.~~

~~The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:~~

[1]~~For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.~~

3.5.3.3.1 First to identical blood type zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

i. local candidates; then to
ii. 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii. 80% or higher PRA candidates on the regional waiting list; then to
iv. 80% or higher PRA candidates on the national waiting list; then to
v. less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi. less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
vii. less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
viii. 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix. 21%-79% PRA candidates on the regional waiting list; then to
x. 21%-79% PRA candidates on the national waiting list.

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and, then, to blood type A and AB zero antigen mismatched candidates, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all pediatric and sensitized adult candidates (CPRA > 20%) who are blood type compatible zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below:

i. local candidates; then to
ii. 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii. 80% or higher PRA candidates on the regional waiting list; then to
iv. 80% or higher PRA candidates on the national waiting list; then to
v. less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

vi. less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
vii. less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
viii. 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix. 21%-79% PRA candidates on the regional waiting list; then to
x. 21%-79% PRA candidates on the national waiting list.

3.5.3.4 Kidney/Non-Renal Exception. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNet℠ or through the Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients.[1] If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.13.2 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to

[1] For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNet℠, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet℠. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. Please refer to Policy 3.8.3 (Allocation Sequence).An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.

3.5.4.1 Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate Member for the candidate with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit), 3.8.3.4 Organ Offer Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor[4], six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[4]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, liver, or pancreas. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver, or pancreas. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than six.

NOTE: The amendments to Policies 3.5.3.4 (Kidney/Non-Renal Exception), 3.5.3.5 (Organ Offer Limit), 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates), 3.55 (Payback Requirements), 3.5.5.1 (Deferment of the Kidney/Non-Renal Exception), 3.5.5.1.2 (Deferment of Voluntary Arrangements) shall be effective pending notice to the members and programming on UNet®. (Approved at the November 8-9, 2010 Board of Directors Meeting)

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts

~~accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.~~

~~NOTE: The amendment to Policy 3.5.5.3. (Kidney Payback Debt Limit), shall be effective pending notice to the membership. (Approved at the June 28-29, 2011 Board of Directors Meeting)~~

~~3.5.6 Geographic Sequence of Deceased Kidney Allocation~~. ~~In general, kidneys are to be allocated locally first, then regionally, and then nationally.~~

~~3.5.6.1 Local Allocation.~~ ~~With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to candidates within the local unit where the kidneys are procured.~~

~~3.5.6.2 Regional Allocation.~~ ~~If a standard donor kidney is not accepted by any of the local transplant centers for local candidates, the kidney is to be allocated next via the regional list consisting of all candidates listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When a standard donor kidney is allocated regionally, it is to be offered to Members for specific candidates in the region according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate in the region who has been assigned the highest number of points. With all regionally-shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for standard kidney allocation. If a local potential recipient(s) who has agreed to receive expanded criteria donor kidneys is not identified (*i.e.*, a match run and process for notifying the appropriate transplant program(s) initiated) within six hours post cross clamping of the donor aorta, the kidney is to be allocated next via the regional list consisting of all candidates who have agreed to receive expanded criteria donor kidneys listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When an expanded criteria donor kidney is allocated regionally, it is to be offered to Members for specific candidates in the region according to the point system described in Policy 3.5.12 in descending point order beginning with the candidate who has agreed to receive expanded criteria donor kidneys in the region who has been assigned the highest number of points. With all regionally-shared expanded criteria donor kidneys, the Organ Center will advise the OPO for the~~

~~transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for expanded criteria kidney allocation.~~

~~3.5.6.3 National Allocation.~~ ~~If a standard donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates in the other Regions nationally according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for standard donor kidney allocation. If an expanded criteria donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates who have agreed to receive expanded criteria donor kidneys in the other Regions nationally according to the point system described in Policy 3.5.12 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared expanded criteria donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for expanded criteria donor kidney allocation.~~

~~3.5.6.4 Regions.~~ ~~Members belong to the Region in which they are located. The Regions are as follows:~~

~~Region 1 – Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont~~
~~Region 2 – Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia~~
~~Region 3 – Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico~~
~~Region 4 – Oklahoma, Texas~~
~~Region 5 – Arizona, California, Nevada, New Mexico, Utah~~
~~Region 6 – Alaska, Hawaii, Idaho, Montana, Oregon, Washington~~
~~Region 7 – Illinois, Minnesota, North Dakota, South Dakota, Wisconsin~~
~~Region 8 – Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming~~
~~Region 9 – New York~~
~~Region 10 – Indiana, Michigan, Ohio~~
~~Region 11 – Kentucky, North Carolina, South Carolina, Tennessee, Virginia~~

3.5.7 Double Kidney Allocation. Kidneys from adult donors must be offered singly unless the donor meets at least two of the following conditions and the OPO would not otherwise use the kidneys singly:

(i) Donor age greater than 60 years;
(ii) Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission;
(iii) Rising serum creatinine (greater than 2.5 mg/dl) at time of retrieval;
(iv) History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus);
(v) Adverse donor kidney histology (defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%).

Kidneys offered for double kidney allocation will be allocated, first locally, then regionally, and then nationally, according to the sequence and point system described in Policies 3.5.6 and 3.5.11.

3.5.8 Expanded Criteria Donor Kidney Allocation. Kidneys from expanded criteria donors must be offered for candidates who have agreed to receive these organs in accordance with the geographic sequence of deceased kidney allocation set forth in Policy 3.5.6 and pursuant to the point system described in Policy 3.5.12.

3.5.9 Minimum Information/Tissue for Kidney Offer.

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

i. Donor name and Donor I.D. number, age, sex, and race;
ii. Date of admission for the current hospitalization;
iii. Diagnosis;
iv. Blood type;
v. ABO subtype when used for allocation;
vi. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A;
vii. Current history of abdominal injuries and operations;
viii. Pertinent past medical or social history;
ix. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
x. Final urinalysis;
xi. Final BUN and creatinine;
xii. Indications of sepsis;
xiii. Assurance that final blood and urine cultures are pending;
xiv. Serologies as indicated in 2.2.4.1 qualified specimens preferred as noted in Policy 2.2.3.1);
xv. Current medication and transfusion history;
xvi. Recovery blood pressure and urine output information;
xvii. Recovery medications;
xviii. Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
xix. Description of typing material available, including, as a minimum for each kidney:
- One 7 to 10ml. clot (red topped) tube for ABO Verification, plus
- 2 ACD (yellow top) tubes

- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available

xx. Warm ischemia time and organ flush characteristics; and

xxi. Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood

3.5.9.2 Desirable Information for Kidney Offers. With each kidney offer, the Host OPO or donor center is encouraged to provide the recipient center with the following biopsy information for all ECD kidneys and for all non-ECD kidneys at the request of the accepting surgeon. To ensure an optimal kidney biopsy, it is *recommended* that:

(i) the wedge technique be used;
(ii) the sample measures approximately 10mm (length) x 5mm (width) x 5mm (depth);
(iii) a minimum of 25 glomeruli are captured in the sample; and
(iv) a frozen section slide or the biopsy material accompanies the kidney for review.

3.5.10 Reserved

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the Match System, all candidates who have an ABO blood type that is compatible with that of the donor and who are listed as active on the Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNet^{SM}; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNet^{SM}, including whether the candidate met the following criteria.

- measured (actual urinary collection) or calculated or creatine clearance or GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of chronic maintenance dialysis (defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) candidate in a hospital based, independent (non-hospital based), or home setting).

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. While not required for purposes of initiating waiting time, programs shall report whether or not pediatric candidates are on dialysis, and if on dialysis, a dialysis start date. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

NOTE: The amendments to Policy 3.5.11.1 (Time of Waiting) shall be effective pending notice to the members and programming on UNet[sm]. (Approved at the November 8-9, 2010 Board of Directors Meeting)

3.5.11.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a candidate based on the number of mismatches between the candidate's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

- 2 points if there are no DR mismatches, as defined in the table below or;
- 1points if there is 1 DR mismatch as defined in the table below.

HLA Mismatch Definitions*

Mismatch Category	**# HLA Locus Mismatches**		
	A	**B**	**DR**
0 ABDR MM	0	0	0
0 DR MM	0	1	0
	0	2	0
	1	0	0
	1	1	0
	1	2	0
	2	0	0
	2	1	0
	2	2	0
1 DR MM	0	0	1
	0	1	1
	0	2	1
	1	0	1
	1	1	1
	1	2	1

	2	0	1
	2	1	1
	2	2	1

- Antigens that are considered to be equivalent for matching purposes are currently shown in Appendix A to Policy 3.

There is a pair of antigens at each HLA locus. Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus (i.e., When only one of the antigens in the pair at an HLA locus is identified, the other antigen is presumed to be identical). For example, a donor typed as A2, A-(blank) would be considered A2, A2. In the following example, the recipient would receive 2 points for having a zero, DR mismatch (no mismatches at DR locus) because the recipient would not recognize any DR donor antigens as foreign.

Donor Phenotype	Recipient Phenotype
A23, A- (blank)	A1, A9
B7, B8	B7, B8
DR, DR4	DR1, DR4

3.5.11.3 Sensitized Wait List Candidates - Calculated PRA (CPRA). CPRA is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. Sensitized Waiting List candidates with defined unacceptable HLA antigens that yield a CPRA of 80% or greater will be assigned 4 points. Each transplant center may define the criteria for unacceptable antigens that are considered as contraindications for transplantation. Unacceptable antigens that are defined by laboratory detection of HLA specific antibodies must be determined using at least one solid phase immunoassay using purified HLA molecules. It is the prerogative of the transplant center to establish criteria for additional unacceptable antigens, such as repeat transplant mismatches. The CPRA will be calculated automatically when the unacceptable antigens are listed or updated on the Waiting List. The CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.

3.5.11.4 Medical Urgency. No points will be assigned to candidates based upon medical urgency for regional or national allocation of kidneys. Locally, the candidate's physician has the authority to use medical judgment in assignment of medical urgency points if there is only one renal transplant center. When there is more than one local renal transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.

3.5.11.5Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. These points shall be assigned when the candidate is registered on the Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after Cardiac Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supersede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney Pancreas Candidates).

3.5.11.6 Prior Living Organ Donors A candidate will receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate's physician provides all of the following information to the OPTN Contractor:
   - The name of the recipient of the donated organ or organ segment
   - The name of the recipient's Transplant Program
   - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

3.5.12 The Point System for Expanded Criteria Donor Kidney Allocation. When information about an expanded criteria donor is entered into the Match System, all candidates who have agreed to receive expanded criteria donor kidneys, have an ABO blood type that is compatible with that of the donor, and who are listed as active on the Waiting List will be assigned points and priority as follows:

3.5.12 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNet℠; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNet℠, including whether the candidate met the following criteria.

- measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of dialysis.

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

3.5.12.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.

3.5.13 Choice of Right Versus Left Donor Kidney. Except in the case of donor kidney(s) offered for zero antigen mismatched candidates under Policy 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) or for kidney and non-renal organ transplantation, the recipient center offered a kidney for a candidate based upon priority on the waiting list may select which of the two kidneys it will receive, if both kidneys from the donor are transplantable.

3.5.14 Broad and Split Antigen Specificities. HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in Appendix 3A. Appendix 3A will be updated annually by the Histocompatibility Committee. For matching purposes, split antigens not on this list will be indicated on the Waiting List as the parent antigens and will match only with the corresponding parent antigens. Laboratories are encouraged to assign all splits.

3.5.15 Local Conflicts. Regarding allocation of kidneys, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Kidney and Pancreas Transplantation Committee and Board of Directors.

3.5.16 Allocation of Deceased Kidneys with Discrepant HLA Typings. Allocation of deceased kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the donor, the kidney may be allocated in accordance with the original HLA typing, or the recipient center may reallocate the kidney locally, according to Policy 3.5.

3.5.17 Prospective Crossmatching. A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

3.1.13 Definition of Directed Donation – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept a kidney from a donor with a KDPI score >85%~~an ECD~~ or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
  - ABO;
  - ABO subtype when used for allocation;
  - Serologies;
  - Donor HLA and candidate's unacceptable antigens;
  - Height; and
  - Weight.

3.2.4.2 ~~Waiting Time~~ Reinstatement for Kidney Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor kidney, the candidate may be reinstated to the Waiting List and retain the previously accumulated waiting time without interruption for that transplant only. The EPTS Score will also be calculated without interruption. For purposes of this policy, immediate and permanent non-function shall be defined as: (1) kidney graft removal within the first ninety (90) days of transplant evidenced by a report of the nephrectomy for the transplanted kidney or (2) kidney graft failure within the first ninety (90) days of transplant evidenced by documentation that the candidate is either: (a) on dialysis, or (b) has measured creatinine clearance/calculated GFR less than or equal to 20 ml/min on the date that is ninety (90) days following the candidate's kidney transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Renal Waiting Time Reinstatement Form and the documentation described above. The OPTN contractor will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

3.3.5 Transplant Recipient Backup for Organ Offers. OPOs are encouraged to make backup offers for all organs. A backup offer shall be considered

equivalent to an actual organ offer and the backup center shall have one hour to respond after receiving the minimum data required for an organ offer pursuant to Policies ~~3.5.9~~3.5.7.4 (Minimum Information/Tissue for Kidney Offer), 3.6.9, 3.7.12 and/or 3.8.2.2. Refusal to consider or respond to a backup offer will be considered as a refusal to accept the organ. The backup center may later refuse to accept the organ based on medical or logistical criteria. The backup center should be notified promptly of any change in donor status or organ disposition

3.4.2 Time Limit For Acceptance. A transplant center, or its designee, must access donor information within UNet^{SM} within one hour of receiving the initial organ offer notification. If UNet^{SM} is not accessed within one hour by the transplant center or its designee, the offer will be considered refused. Once the appropriate donor information is provided as described in Policies ~~3.5.9~~ 3.5.7.4 (Minimum Information/Tissue for Kidney Offer), 3.6.9, 3.7.12, and 3.8.2.2, a transplant center shall be allowed one hour from the time of accessing the donor information, except as otherwise provided in Policies 3.5.7.1 (Mandatory Sharing) ~~3.5.3.5 (Time Limit)~~ and 3.8.3.4 (Organ Offer Limit), in which to communicate its acceptance or refusal of the organ. After one hour elapses, or shorter period as defined under Policies 3.3.5 and 3.8.3.4, without a response, the offer will be considered refused and the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority on the match list.

3.8.1.4 Criteria to Accrue Kidney-Pancreas Waiting Time. In order to be eligible to accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate must:

- Qualify for a solitary kidney transplant according to the criteria used for a kidney candidate to accrue waiting time specified in Policy 3.5.4 (Waiting Time) ~~Policy 3.5.11.1 (Time of Waiting);~~ and
- Meet *one* of the following criteria:
    1. On insulin and C-peptide less than or equal to 2 ng/mL; or
    2. On insulin and C-peptide greater than 2 ng/mL and BMI less than or equal to the maximum allowable BMI.
        a. Upon implementation, the maximum allowable BMI shall be 28 kg/m^2.
        b. The OPTN contractor will review the kidney-pancreas waiting list to determine the percentage of candidates who meet criteria 2 above every six months beginning six months after implementation.
        c. Whenever such reviews determine that the percentage of active candidates on the kidney-pancreas waiting list who meet criteria two is greater than fifteen percent, the maximum allowable BMI shall be reduced by 2 kg/m^2.
        d. Whenever such reviews determine that the percentage of active candidates on the kidney-pancreas waiting list who meet criteria two is less than ten percent, the maximum allowable BMI shall

be increased by 2 kg/m^2. The maximum allowable BMI shall not exceed 30 kg/m^2.

e. Whenever the maximum allowable BMI is reduced or increased according to (c) or (d), the new maximum allowable BMI shall be published in the OPTN contractor's evaluation plan, and the OPTN contractor shall notify all member kidney programs and all member pancreas programs of the change.

Candidates who do not meet these criteria will not be eligible for waiting time for a kidney-pancreas offer on a match run. Once a candidate qualifies for waiting time according to the criteria above, the candidate will remain qualified for SPK waiting time, regardless of any changes to the maximum allowable BMI.

Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria on the dates submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor.

3.8.3.2 Blood Type O Kidney-Pancreas Allocation. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.5.5 (Blood Type Permissibility) ~~Policy 3.5.2 (ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients)~~, unless there is a zero antigen mismatch between the candidate and donor and the candidate has a CPRA greater than or equal to 80% as defined in Policy 3.8.4.1 (CPRA).

3.8.3.5 Organ Offer Limits. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNet^{SM} or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients[2] according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

[2] For the purposes of Policy 3.8.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 (Kidney Allocation Classifications and Rankings) and pancreas allocation under Policy 3.8.3.2, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

~~If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNet℠, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet℠. No obligation to pay back the pancreas or the kidney will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.~~

3.8.4.1 CPRA. To receive priority in the allocation of isolated pancreata or kidney-pancreas combinations based upon CPRA, candidate unacceptable HLA antigens sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA) ≥ 80%)[2] must be entered into UNet℠. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.

[2] For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.1 (Calculated Panel Reactive Antibody) ~~Policy 3.5.11.3 (Sensitized Wait List Candidates)~~ for assigning priority in the allocation of deceased donor kidneys.

3.8.4.3 Waiting Time. Within each classification in Policy 3.8.3.2 (Allocation Sequence), candidates will be ranked based on waiting time.

Waiting time for pancreas and pancreas islet candidates begins on the date the candidate is listed for the organ.

Once an adult kidney-pancreas candidate is eligible for kidney-pancreas waiting time according to Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time), waiting time for adult kidney-pancreas candidates begins on the date the candidate is eligible to receive waiting time for a kidney transplant according to Policy 3.5.4 (Waiting Time) ~~3.5.11.1 (Time of Waiting)~~.

For a candidate who is listed for an SPK transplant before his or her 18th birthday, the candidate's waiting time begins on the date the candidate is eligible to receive waiting time for a kidney transplant according to Policy 3.5.4 (Waiting Time) ~~3.5.11.1 (Time of Waiting)~~, regardless of whether the candidate meets the criteria stated in Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time).

Candidates shall continue to accrue waiting time while registered on the waiting list as inactive.

3.9.3 Organ Allocation to Multiple Organ Transplant Candidates. Candidates for a multiple organ transplant where one of the required organs is a heart, lung, or liver shall be registered on the individual Waiting list for each organ. When the candidate is eligible to receive a heart, lung or liver pursuant to Policies 3.6 (Allocation of Livers) and 3.7 (Allocation of Thoracic Organs) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case no payback obligation will be incurred. ~~the organ shall be paid back pursuant to Policy 3.5.4.5 (Payback Requirements)~~. This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For candidates awaiting a combined liver-intestine transplant, please refer to Policy 3.11.4 or Policy 3.6.4.8. For candidates awaiting a combined kidney-pancreas transplant, please refer to Policy 3.8.3 (Allocation Sequence).

6.4.1.1 Requirements for Importing Deceased Donor Organs through a Formal Agreement. The Member importing any deceased donor organ from a foreign entity must:

- Report the event within 72 hours to the Organ Center.
- Allocate the organ using the Match System in accordance with the allocation policy for that organ.
- Provide the minimum required information about the foreign deceased donor organ, as specified in Policies 2 (Minimum Procurement Standards for an Organ Procurement Organization (OPO), ~~3.5.9~~ 3.5.7.4 (Minimum Information/ Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7.12 (Minimum Information for Thoracic Organ Offers, and 3.8.2 (Required Information).
- Comply with the ABO verification requirements in Policies 2 and

3.2.4 (Match System Access).

- Evaluate the organ for transmissible diseases as specified in Policy 4 (Identification of Transmissible Diseases in Organ Recipients).
- Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency of its national government.
- Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

~~**9.6.8** Updated OPO-specific kidney payback debt and credit volumes, including number of short-term payback debts, long-term payback debts, and thresholds for reducing long-term debt (please see Policy 3.5.4.2 (Kidney Payback Debt Limit) for definitions of "short-term debt" and "long-term debt"), for such period(s) as determined appropriate by the POC.~~

12.5.6 Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates (3.5.6.2). The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the rationale used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request. This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement.

~~**12.9.4 Exception for Prior Living Donor Organs.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.~~

12.9.4 Kidney Allocation Priority for Prior Living Organ Donors. Candidates registered for kidney transplant who are prior living organ donors as defined in policy 3.5.5.6 (Prior Living Organ Donors) will receive additional allocation priority as described in policies 3.5.3 (Points) and 3.5.6 (Kidney Allocation Classifications and Rankings)

To read the complete Policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Affected Bylaws Language:

Article VII: Permanent Standing Committees

The OPTN will have the following permanent standing Committees:

- Ethics
- ~~Finance~~
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
- Membership and Professional Standards
- Minority Affairs
- Operations and Safety
- Organ Procurement Organization
- Pancreas Transplantation
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight Committee
- Thoracic Organ Transplantation
- Transplant Administrators
- Transplant Coordinators

The Committees are advisory to the Board of Directors, which makes the final decisions of the OPTN. The standing Committees will provide initial review and analysis of proposed policies and initiatives based on their collective expertise and unique perspectives, and present their recommendations to the Board of Directors.

Committees may also be advisory to each other when Committee interest and expertise overlap. When Committees evaluate proposals jointly, they should present to the Board of Directors either a common recommendation or a report that summarizes the continued disagreement.

Committees may have additional responsibilities as defined by the OPTN Bylaws and Policies. Committees' role in developing policies and standards is further defined in *Article XI: Adoption of Policies* of these Bylaws.

7.6 Finance Committee

In addition to the permanent standing committees listed above, the OPTN will have a Finance Committee to assist in the governance of the OPTN.

The Finance Committee will report to the Board. The Finance Committee will have members, composition, terms, and duties, as may be determined by the President in consultation with the Board of Directors. The President may appoint any number of non-voting Advisors to the

Finance Committee subject to approval by the Board of Directors for terms the President may deem appropriate.

~~7.6~~7.7 Conflicts of Interests

All OPTN ~~standing~~ Committee members must avoid conflicts of interest and the appearance of conflicts of interest. Committee members will be held to the standard for conflicts of interest as described in *Article 2.7: Conflicts of Interests* of these Bylaws.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Affected Bylaws Language:

Appendix D:
Membership Requirements for Transplant Hospitals and Transplant Program

D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as *any* of the following:

1. The inability to serve potential candidates, candidates, ~~or~~ recipients, potential living donors, or living donors for a period of 15 or more consecutive days.
~~2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.~~
~~3~~2. The failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

Given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements for functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

~~**B. Requirements of Functional Inactivity**~~

~~A transplant program must provide written notice to candidates if it does *either or both* of the following:~~

~~1. Inactivates its waiting list or is unable to perform transplants for 15 or more consecutive days.~~
~~2. Inactivates its waiting list or is unable to perform transplants for 28 or more cumulative days over any 365 consecutive day period.~~

B. Review of Member Functional Inactivity

The MPSC may also require, at its discretion, that the member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC.

The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of

these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to 12 months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than 12 months, the member should relinquish designated transplant program status as required in these Bylaws.

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's inactivity.

D.10 Additional Transplant Program Requirements

A. Transplant Program Survival Rates

The MPSC will review a transplant program if it has a low survival rate compared to the expected survival rate for that transplant program. The review will be to determine if the low survival rate can be explained by patient mix or some other unique clinical aspect of the transplant program. The MPSC may conduct a peer visit to the program at member expense and may require the member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the member participate in an informal discussion.

The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

While the precise statistical criteria may be selected by the MPSC, the initial criteria used to identify programs with low patient or graft survival rates will include *all* of the following:

1. The finding that *observed events* minus *expected events* is greater than 3.
2. The finding that the *observed events* divided by *expected events* is greater than 1.5.
3. There exists a one-sided *p value* less than 0.05.

Observed events are deaths or graft losses as reported in UNET[sm] database. *Expected events* are deaths or graft losses as calculated using organ-specific transplant models.

Those programs whose actual observed patient or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to do so will constitute a violation of OPTN obligations.

B. Patient Notification Requirements for Waiting List Inactivation

A transplant program must provide written notice to candidates if it does *either or both* of the following:

1. Inactivates its waiting list or is unable to perform transplants for 15 or more consecutive days.
2. Inactivates its waiting list or is unable to perform transplants for 28 or more cumulative days during any calendar year.

A Transplant Program must provide written notice *each* time it reaches either of the inactive waiting list thresholds listed above. Written notice must include *all* of the following:

1. The reason for the inactivity
2. The expected length of time that the waiting list will be inactive
3. The explanation that during the period of inactivity, organs cannot be accepted on the candidate's behalf at this transplant program
4. The options available to the candidate during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
5. How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
6. A copy of the UNOS Patient Information Letter

Note: If written notice is required because a Transplant Program exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation.

Written notice must be provided within the periods defined in the table below:

For…	**Written Notice Must be Provided…**
Periods of waiting list inactivation scheduled at least 30 days in advance	30 days before inactivity begins.
Periods of waiting list inactivation	No more than 7 days following the initial

scheduled less than 30 days in advance	date of waiting list inactivation.
Any periods of waiting list inactivation related to a cumulative period of inactivation	No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.

~~B~~C. Routine Referral Procedures

Each transplant hospital must develop and follow routine referral procedures for all potential donors. Each transplant hospital is further expected to demonstrate compliance based on an annual medical record review, performed in collaboration with the OPO. Any program found to be out of compliance will be reviewed by the MPSC.

~~C~~D. Candidate Selection Procedures

Each transplant program must establish procedures for selecting transplant candidates and distributing organs efficiently and equitably.

~~D~~E. Donation after Circulatory Death (DCD) Protocols

Each transplant hospital must develop and comply with protocols to facilitate the recovery of organs from DCD donors. Transplant hospital DCD recovery protocols must address the requirements as described in *OPTN Policy 2.0*.

~~E~~F. Veteran's Administration (VA) Dean's Committee Hospitals

VA Hospitals that are Dean's Committee Hospitals and share a common university based transplant team, do not need to submit a separate membership application to the OPTN Contractor, but may be considered members under the university program with which they are affiliated.

Independent VA Hospitals, or VA Hospitals that are not Dean's Committee Hospitals sharing a common university based transplant team, must submit an application and be approved for OPTN membership in order to receive organs for transplantation.

~~F~~G. Relocation or Transfer of Designated Transplant Programs

A designated transplant program may be transferred from one OPTN member transplant hospital to another hospital within the same metropolitan area if the following requirements are met:

1. Both OPTN member transplant hospitals voluntarily consent in writing to the transfer of designated program status and to the transfer of one or more transplant programs from the original facility to the new hospital.
2. The Transplant Surgeon, Transplant physician, immunology, tissue typing and organ procurement services associated with the original transplant hospital must be

available to the new hospital by using most of the same personnel that have been performing these services in the original hospital.

3. The original transplant hospital voluntarily agrees in writing to inactive status for those transplant programs being relocated from the original facility for at least three months and to relinquish its designated status for those programs being relocated until it has attained designated status based solely upon transplants performed at the original facility after the transfer.
4. Programs that have conditionally approval may be transferred to the new hospital along with the designated program, provided that the conditionally approved program requirements in effect at the time of transfer are met.
5. The new hospital must meet the requirements for OPTN transplant hospital member.

Appendix K: Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

K.1 Transplant Program Inactivity

Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- Temporarily lacking required physician or surgeon coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see *Appendix D, Section D.9: Review of Transplant Program Functional Activity* of these Bylaws.

A. Program Component Cessation

Programs that cease performing a specific type of transplant (e.g. the living donor component of a transplant program, or cessation of only pediatric or only adult transplants in a transplant program that performs both), must notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list

- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

Ceased Component*	***All Affected Patients Being Treated or Evaluated by the Transplant Program Including:***
Living Donor Component	• Potential Living Donors • Potential and waitlisted candidates who have already expressed interest in LD
Deceased Donor Component	• Potential and waitlisted deceased donor candidates
Adult Component	• Potential and waitlisted adult candidates • Potential and waitlisted pediatric candidates who may turn 18 during the component cessation period
Pediatric Component	• Potential and waitlisted pediatric candidates

*In instances when a program elects to cease transplant for a subset of patients within a program component, such as infants in a pediatric component, the affected group would be further defined to only include that specific patient population.

For more information about the notification content and timing requirements, see *Appendix K, Section K.3: Long-term Inactive Transplant Program Status* and *Section K.4: Withdrawal of Termination of Designated Transplant Program Status* of these Bylaws.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS bylaw language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Affected Bylaws Language:
Appendix J:
Reserved

~~***Membership and Personnel Requirements for Joint Heart and Lung Programs***~~

~~A designated heart and lung transplant program must have current approval as a designated heart transplant program *and* a designated lung transplant program as described in:~~

- ~~*Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*~~
- ~~*Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*~~

~~Designated heart and lung transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.~~

~~For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.~~

~~**J.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician**~~

~~A heart and lung transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.~~

~~The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below in *Sections J.2* and *J.3*. The primary surgeon and physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Appendix D, Section D.5.B: Surgeon and Physician Coverage* of these Bylaws.~~

~~**J.2 Primary Heart and Lung Transplant Surgeon Requirements**~~

~~A designated heart and lung transplant program must have on site a qualified transplant surgeon who meets the requirements for primary heart transplant surgeon *or* primary lung transplant surgeon as defined in these Bylaws.~~

~~**J.3 Primary Heart and Lung Transplant Physician**~~

~~A designated heart and lung transplant program must have on site a qualified transplant physician who meets the requirements for primary heart transplant physician *or* primary lung transplant physician as defined in these Bylaws.~~

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the “Policy Management” tab, then select “OPTN Bylaws.” To read the complete UNOS Bylaws language visit www.unos.org, click on the “ABOUT US” box at the top of the screen, and then, in the left margin under “Governance,” select “Bylaws.”

Affected Policy Language:

~~**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~~

7.1.~~7~~6 ~~Although it is recognized that~~ **Eligible Death Definition**. The OPO must maintain documentation used to exclude any patient from the eligible data definition. ~~t~~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 the following:~~ with all the following characteristics:

- 75 years old or younger;
- Is legally declared dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law;
- Body Weight 5 kg or greater;
- Body Mass Index (BMI) of 50 kg/m^2 or less;
- Has at least one kidney, liver, heart or lung that is "deemed to meet the eligible data definition as defined below:
  - The kidney would be initially deemed to meet the eligible data definition unless the donor has one of the following:
    - > 70 years of age
    - Age 50-69 years with history of Type 1 diabetes for >20 years
    - Polycystic kidney disease
    - Glomerulosclerosis ≥ 20 % by kidney biopsy
    - Terminal serum creatinine greater than 4/0 mg/dl
    - Chronic Renal Failure

- No urine output ≥ 24 hours

- The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:
  - Cirrhosis
  - Terminal total bilirubin ≥ 4 mg/dl
  - Portal hypertension
  - Macrosteatosis ≥ 50% or fibrosis ≥ stage II
  - Fulminant hepatic failure
  - Terminal AST/ALT > 700 U/L
- The heart would be initially deemed to meet the eligible data definition unless the donor has one of the following:
  - > 60 years of age
  - ≥ 45 years of age with a history of ≥10 years of HTN or ≥10 years of type 1 diabetes
  - History of Coronary Artery Bypass Graft (CABG)
  - History of coronary stent/intervention
  - Current or past medical history of myocardial infarction (MI)
  - Severe vessel diagnosis as supported by cardiac catheterization (i.e. >50% occlusion or 2+ vessel disease)
  - Acute myocarditis and/or endocarditis
  - Heart failure due to cardiomyopathy
  - Internal defibrillator or pacemaker
  - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
  - Serial echo results showing severe global hypokinesis
  - Myxoma
  - Congenital defects (whether surgically corrected or not)
- The lung would be initially deemed to meet the eligible data definition unless the donor has one of the following:
  - Age > 65 years of age
  - Diagnosed COPD (eg; emphysema)
  - Terminal PaO_2/FiO_2 <250 mmHg
  - Asthma (with daily prescription)
  - Asthma is the cause of death
  - Pulmonary Fibrosis
  - Previous lobectomy
  - Multiple blebs documented on Computed Axial Tomography (CAT) Scan
  - Pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures
  - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an Eligible Death unless the donor meets any of the following criteria:

- The donor has no suitable organ for transplant (as defined above), or;

- the donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplantation, or;
- if the donor exhibits any of the following:

    - Active infections ~~(~~with a specific diagnoses;~~) [Exclusions to the Definition of Eligible]~~
    - Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal 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 Disseminated 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
    - No discernable cause of death

7.1.7 **Imminent Neurological Death.** The OPO must maintain documentation used to exclude any patient from the imminent neurological death data definition. Imminent Neurological Death is defined as a death of a patient:

- who meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law, and
- who has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital

chart, has no observed spontaneous breathing and has an absence of at least two additional brain stem reflexes.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurological death.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Affected Policy and Bylaws Language:

3.2.1.8.1 Permissible Modifications Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in removing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error. <u>This also applies where an islet recipient has re-registered on the islet waiting list and is eligible for previously accrued waiting time per policy 3.8.7.2 (Accrual of Waiting Time).</u>
- An error occurred in listing, modifying, or renewing the candidate's waiting list record for a Status 1 liver, Status 1A heart, or Priority 1 pediatric lung candidate and the Transplant Program requests a modified waiting time to correct any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate needs a second organ while waiting for a heart, liver, or lung, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.
- The candidate needs a second organ while waiting for a kidney, pancreas, or intestine, routine alternative therapies are not possible, the other Transplant Programs within the OPO and the OPO itself agree to the modified waiting time, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies. If an application does not comply with the requirements of Policy 3.2.1.8, then the OPTN Contractor will neither implement the requested waiting time modifications nor forward the application for review.

3.8 Pancreas Allocation Policy

Purpose: The following policies describe the process for listing pancreas, kidney-pancreas, and pancreas islet candidates and for allocating organs to pancreas, kidney-pancreas, and pancreas islet candidates.

Key Terms:

Body Mass Index (BMI) - A measure of body size, calculated as weight in kilograms divided by height in meters squared.

Calculated Panel Reactive Antibody (CPRA) - The percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.

C-Peptide- A byproduct of insulin production, usually by the pancreas. The level of C-peptide is a gauge of how much insulin is being produced in the body.

Creatinine Clearance (CrCl)- A measure used to determine kidney function, the CrCl indicates the volume of serum or plasma that would be cleared of creatinine by one minute's excretion of urine.

Glomerular Filtration Rate (GFR) - A measure used to determine kidney function, the GFR indicates the kidney's ability to filter and remove waste products.

Islet Infusion – An infusion of islets from a single deceased donor. If a recipient receives islets from multiple donors simultaneously, then each donor's islets must be counted as a separate infusion.

Pancreas-Alone Transplant – A type of pancreas transplant where the pancreas is transplanted without any other organs

Simultaneous Pancreas-Kidney (SPK) Transplant - A type of pancreas transplant where the pancreas and kidney from the same donor are transplanted at the same time (also known as a combined kidney-pancreas transplant)

3.8.7.2 Accrual of Waiting Time.

A candidate will begin to accrue islet waiting time when the candidate is registered on the waiting list. Candidates accrue waiting time while registered at an active or inactive status.

An islet candidate will retain waiting time through three registrations at the registering center, including the waiting time from the previous registrations and any intervening time. After a candidate has received a

series of three islet infusions at the registering hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions,

~~A candidate is eligible to accrue waiting time:~~

- ~~while listed in an active or inactive status; and~~
- ~~until the candidate has received a maximum of three islet infusions.~~

~~Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.~~

3.8.7.4 Process for Re-Allocating Islets. If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers, and
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run~~,~~.

- ~~Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.~~

3.8.7.5 Removal from the Pancreas Islet Waiting List~~.~~

The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving each ~~his/her third~~ islet infusion.

OPTN Bylaws
Article I: Membership
1.2 Transplant Hospital Members

D. Registration Fees

Transplant hospital members are responsible for the payment of an OPTN Registration Fee for each transplant candidate ~~listed~~ registered by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

An additional registration fee will be due for a transplant candidate if:

- A candidate is given an inactive status or removed from the waiting list without receiving a transplant and is not placed back on the list within the 90-day grace period.
- A recipient has received a transplant but is put back on the waiting list for another transplant. However, no additional registration fee will be due for an islet candidate who is removed and, if the option to re-register is offered during the removal process, immediately re-registered for an islet infusion.
- A candidate is transferred to a transplant hospital *outside* the original OPO Donation Service Area. A new registration fee must be paid by the receiving hospital.
- The potential recipient is listed at multiple transplant hospitals. A registration fee must be paid by each transplant hospital that places the candidate on the waiting list.

Members who ~~list~~ register candidates needing more than one organ (for example, kidney and pancreas) are only charged one registration fee.

OPTN Bylaws, Appendix G

G.4 Requirements for Designated Pancreatic Islet Transplant Programs

All Pancreatic Islet Transplant Programs must meet the following criteria:

1. All of the requirements of a Designated Pancreas Transplant Program as defined in the sections above *or* meet the criteria for an exception as detailed in Section *G.4.E: Programs Not Located at an Approved Pancreas Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

~~A.~~ ~~Reporting~~

~~The Program must submit data to the OPTN Contractor for all donors, potential transplant recipients, and actual transplant recipients using the required forms.~~

~~Pending development of standardized data forms for pancreatic islet transplantation, the Program must maintain patient logs and provide them to the OPTN Contractor every 6 months. The patient logs must be cumulative and must include for each transplant performed:~~

1. ~~The patient name~~
2. ~~Social security number~~
3. ~~Date of birth~~
4. ~~Donor ID~~
5. ~~Patient status (alive or dead)~~
6. ~~Whether the pancreas was allocated for islet or whole organ transplantation~~

~~For each pancreas allocated to the Program for islet transplantation, the Program must report to the OPTN Contractor if the islets were used for transplantation. If the islets were not used in transplantation, the Program must report the reason and disposal method, together with other information requested on the Pancreatic Islet Donor Form.~~

A~~B~~. Transplant Facilities

The Program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The Program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

B~~C~~. Expert Medical Personnel

The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. It is further recommended that the Program have on site or adequate access to:

1. A board-certified endocrinologist
2. A physician, administrator, or technician with experience in compliance with FDA regulations

3. A laboratory-based researcher with experience in pancreatic islet isolation and transplantation

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

C~~D~~. Islet Isolation

Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.

D~~E~~. Programs Not Located at an Approved Pancreas Transplant Program

A Program that meets all requirements for a Designated Pancreatic Islet Transplant Program but is not located at a hospital approved as a Designated Pancreas Transplant Program may qualify as a Pancreatic Islet Transplant Program if the following additional criteria are met:

1. The Program demonstrates a documented affiliation with a Designated Pancreas Transplant Program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.
2. The Program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The Program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."