

3.0 ORGAN DISTRIBUTION

The following policies apply to the allocation of organs for transplantation.

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.1 Pancreas Organ Allocation. For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.34 or Policy 3.8.1.6 and for whom there is a zero antigen mismatch with the donor. Within each Patient Waiting List, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.34. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.34 the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m², shall be allocated regionally and then nationally, or for patients listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence: Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.4 below:

3.8.1.1 Regional Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.75.

3.8.1.2 National Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.75.

3.8.1.3 Facilitated Pancreas Allocation. In the event that the UNOS Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of patients has by that time been exhausted, the pancreas shall be offered through the UNOS Organ Center for patients listed with those transplant centers that have recorded in writing their desire, to participate in the UNOS system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to patients who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates

shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.45.

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to UNOS Policy 3.8.1.6 in the event there is a patient on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system to UNOS in writing.

3.8.1.4 Islet Transplantation. If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m² and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, or 3.8.1.3, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

If the donor is greater than 50 years old or has BMI greater than 30 kg/m², and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation, and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

3.8.1.5 Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. If after islet processing is completed, the islet preparation is medically unsuitable for the candidate, the islets from that pancreas will be reallocated to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows. The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the OPTN/UNOS Board by the OPTN/UNOS Kidney & Pancreas Transplantation Committee KPTC within three years. Two active status codes will be used, Status 1 (Urgent) and Status 2 (Non-Urgent). At the regional and national level islet allocation shall be as follows:

- ~~Matching~~ ~~0 HLA Mismatch~~ ~~3 points~~
~~1 HLA Mismatch~~ ~~2 points~~
~~2 HLA Mismatch~~ ~~1 point~~
~~3-6 HLA Mismatch~~ ~~0 points~~

~~Status 1 A patient that receives a clinical islet transplant becomes a Status 1 for a three week period. (Recipients need islets from four or more donors within three weeks). Status 1 islet candidates shall have priority over Status 2 candidates at each level of allocation, (i.e., local, regional, then national).~~

~~Status 2 All patients on the clinical islet transplant list who do not meet the Status 1 criteria.~~

- **Waiting Time**

Waiting time shall begin when a patient is placed on the UNOS Patient Waiting List. Waiting time will accrue for a patient until he/she has received a maximum of three islet infusions or the transplant center removes the patient from the waiting list, whichever is the first to occur. If the patient is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew. Waiting time as a Status 1 begins when the patient becomes a Status 1 and continues until they are no longer a Status 1. If a patient returns to a Status 2, their entire waiting time continues. One point will be assigned to the patient waiting for the longest period with fractions of points assigned proportionately to all other patients, according to their relative waiting time. For example, if there are 75 patients waiting for islets, the patient waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75-60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local or regional waiting list. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

NOTE: The amendments to Policy 3.8.1 (Pancreas Organ Allocation), above shall be implemented following programming on the UNOS system. The amendments in bold are from the November 2003 meeting and unbolded amendments are from the June 2004 meeting.

3.8.1.6 Mandatory Sharing of Zero Antigen Mismatch Pancreata. In the event there is a patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate UNOS member for any highly sensitized patient waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.3.4 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then, be offered to the appropriate UNOS member for any highly sensitized (i.e. panel reactive antibody (PRA) level \geq 80%) patient waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a patient listed on the Host OPO's local patient waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has panel reactive antibody (PRA) level of 80% or greater

based on historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. In this event, for local allocation, the pancreas shall be offered for the mismatched patient(s) with PRA greater than or equal to 80% and a negative preliminary crossmatch (based upon length of time waiting if more than one patient meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally and nationally.

NOTE: The amendments to Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) above shall be implemented following programming on the UNOS system.

3.8.1.6.1 Time Limit. 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 the UNOS Organ Center. The UNOS Organ Center will attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable, for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.5 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally). The period of time allowed for acceptance of zero antigen mismatched pancreas offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four-hour period for placement of zero mismatched donor pancreata. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. In the event the Host OPO declines the opportunity to allocate the organ(s) locally, then the UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will document each offer and each response.

3.8.2 Waiting Time Adjustment. Waiting time accrued by a transplant candidate for one or more organs shall be transferred as follows if it is determined that the patient requires another organ or organ combination:

- (i) Waiting time accrued by a kidney transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for a combined kidney-pancreas transplant if it is determined that the patient requires a combined kidney-pancreas transplant.
- (ii) Waiting time accrued by a kidney transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the patient requires a pancreas transplant.
- (iii) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the patient is suitable for a pancreas alone transplant.
- (iv) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the patient is suitable for a kidney alone

- transplant.
- (v) Waiting time accrued by an isolated pancreas transplant candidate while registered on the UNOS Patient Waiting List shall not be assigned to the listing for a combined kidney-pancreas transplant.
 - (vi) Waiting time accrued by an isolated pancreas transplant candidate while registered on the UNOS Patient Waiting List shall not be assigned to the listing for an isolated kidney transplant.

3.8.3 Inclusion of HLA Data. Recipient HLA information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the UNOS Patient Waiting List.

3.8.4 Regional or National Allocation to Alternate Recipients. For a pancreas that is shared regionally or nationally, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points at that center to seek alternate patients on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that patient. Selection of alternate patients must be according to the UNOS pancreas allocation policy.

3.8.5 Minimum Information for Pancreas Offers.

3.8.5.1 Essential Information Category. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

- (i) Donor name and OPTN Donor I.D. number, age, sex, race and weight;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (iv) Blood type;
- (v) Current history of abdominal injuries and operations including pancreatic trauma;
- (vi) Pertinent past medical or social history including pancreatitis;
- (vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
- (viii) Indications of sepsis;
- (ix) Pre-or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (x) Current medication and transfusion history;
- (xi) Blood glucose;
- (xii) Amylase;
- (xiii) Insulin protocol;
- (xiv) Alcohol use (if known);
- (xv) Familial history of diabetes.

3.8.6 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased. If a pancreas transplant candidate on the UNOS Patient Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all pancreas waiting lists and shall notify UNOS within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the patient is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

3.8.7 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the patient may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and

permanent non-function shall be defined as pancreas graft failure resulting in removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Pancreas Waiting Time Reinstatement Form and documentation, including but not limited to, the patient operative report. UNOS will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

3.8.8 Prospective Crossmatching. A prospective crossmatch is mandatory for all patients, 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.

NOTE: New Policy 3.8.8 (Prospective Crossmatching) shall be effective January 1, 2005.