

### 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.

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)

#### 3.8.1 Pancreas and Kidney-Pancreas Listing and Qualifying Criteria

**3.8.1.1 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

**3.8.1.2 Previous Kidney Donor Antigens Considered “Self” Antigens in Pancreas Match Runs.** Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate's prior kidney donor's antigens, which will then be considered “self” antigens in pancreas match runs. In the event a candidate's prior kidney donor's antigens are entered, the match system for pancreas allocation will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are entered into UNet<sup>SM</sup>. Mismatches Antigens that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match-run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.

**3.8.1.3 Combined Kidney-Pancreas Waiting List Criteria.** Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.

**3.8.1.4 Criteria to Accrue Kidney-Pancreas Waiting Time Qualifying Criteria.** 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 3.5.11.1 (Time of Waiting); and
- Meet one of the following criteria:
  1. On insulin and  $\epsilon$ C-peptide less than or equal to 2 ng/mL; or
  2. On insulin and  $\epsilon$ 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<sup>2</sup>.
- 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<sup>2</sup>.
- 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<sup>2</sup>. The maximum allowable BMI shall not exceed 30 kg/m<sup>2</sup>.
- 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.

**3.8.1.4.1 Exceptions.** Candidates listed for an SPK transplant on or before their 18<sup>th</sup> birthday do not have to meet SPK qualifying criteria.

### **3.8.2 Required Information**

**3.8.2.1 Inclusion of HLA Data.** Recipient-Candidate HLA (at least 1 A, 1 B, and 1 DR antigen) information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the Waiting List.

**3.8.2.2 Essential Information for Pancreas Offers.** 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:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;
5. ABO subtype when used for allocation;
6. Current history of abdominal injuries and operations including pancreatic trauma;
7. Pertinent past medical or social history including pancreatitis;
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
9. Indications of sepsis;

10. Serologies as indicated in Policies 2.2.4.1 and (qualified specimens preferred as noted in Policy 2.2.3.1):
11. Current medication and transfusion history;
12. Blood glucose;
13. Amylase;
14. Insulin protocol;
15. Alcohol use (if known);
16. Familial history of diabetes; and
17. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRB1, and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A.

**3.8.2.3 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.

### **3.8.3 Allocation Sequence**

#### **3.8.3.1 Order of Allocation to Pancreas, Kidney-Pancreas, and Kidney Candidates.**

The Host OPO must offer organs from the combined pancreas/kidney-pancreas match run through the local pancreas and kidney-pancreas candidates as described in Policy 3.8.3.2 (Allocation Sequence) before offering organs to any isolated kidney candidates.

**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 3.5.2 (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).

**3.8.3.23 Allocation Sequence.** Pancreata, kidney-pancreas combinations, and pancreas islets from donors 50 years of age or less and who have a BMI less than or equal to 30 kg/m<sup>2</sup> shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA ≥80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
5. Local pancreas and kidney-pancreas candidates;
6. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA ≥ 80%;
7. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
8. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally regionally) with a CPRA ≥ 80%;
9. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally);
10. Local pancreas islet candidates;
11. Regional pancreas islet candidates;
12. National pancreas islet candidates.

Pancreata, kidney-pancreas combinations, and pancreas islets from donors

greater than 50 years of age or from donors who have a BMI greater than to 30 kg/m<sup>2</sup> shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA  $\geq$  80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA  $\geq$ 80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA  $\geq$  80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA  $\geq$  80%;
5. Local pancreas and kidney-pancreas candidates;
6. Local pancreas islet candidates;
7. Regional pancreas islet candidates;
8. National pancreas islet candidates;
9. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA  $\geq$  80%;
10. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
11. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally regionally) with a CPRA  $\geq$  80%;
12. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally).

In the event that a kidney is not available at the time of the organ offer, the OPO may offer the pancreas to pancreas-alone candidates only.

**3.8.3.34 Facilitated Pancreas Allocation.** In the event that the 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 candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for pancreas-alone candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered to pancreas-alone candidates listed at transplant centers participating in the facilitated pancreas option according to the sequence in Policy 3.8.3.2 (Allocation Sequence), ~~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 Waiting List as inactive.

- ~~Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%);<sup>1</sup>; 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 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~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 and (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate 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 in writing.

**3.8.3.4.5 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<sup>SM</sup> or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients<sup>1</sup> 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:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy ~~3.8.3.23-8.4~~, 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 10<sup>th</sup> 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<sup>SM</sup>, 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<sup>SM</sup>. No obligation to pay back the pancreas 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.

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

### **3.8.4 Determinants for Scoring**

**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)  $\geq$  80%)<sup>2</sup> sufficient to yield CPRA  $\geq$  80%) must be entered into UNet<sup>SM</sup> ~~as described in Policies 3.8.1.1 – 3.8.1.4.~~ Pancreata from donors with antigens included among

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<sup>1</sup> For the purposes of Policy 3.8.3.3, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

<sup>2</sup> 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 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

the unacceptable antigens for a candidate will not be offered for that candidate.

**3.8.4.2 Zero antigen mismatches.** To receive priority in the allocation of pancreata or kidney-pancreas combinations based on a zero mismatch between the candidate and the donor, the candidate must meet the following 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.

**3.8.4.3 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 was 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 3.5.11.1 (Time of Waiting).~~met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min).~~

~~If For a candidate who is listed for an SPK transplant on or before his or her 18<sup>th</sup> birthday qualifies for an SPK, then~~ the candidate's waiting time begins on the date the candidate is eligible to receive waiting time for a kidney transplant according to Policy 3.5.11.1 (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).~~on the earlier date of:~~

- ~~the date the candidate met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min); or~~
- ~~the date of listing.~~

~~If a candidate is listed for an SPK transplant on or before his or her 18<sup>th</sup> birthday does not qualify for an SPK, then waiting time begins at the date of listing.~~

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

**3.8.5 Waiting Time Adjustments**

**3.8.5.1 Waiting Time Adjustments.** Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).

~~Waiting time accrued by a combined kidney-pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for an isolated pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).~~

Waiting time accrued by a combined kidney-pancreas transplant candidate while registered on the waiting list will be assigned to the listing for an isolated kidney transplant or an isolated pancreas transplant.

~~Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated pancreas transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).~~

Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list will be assigned to the listing for an isolated pancreas transplant. Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list will be assigned to the listing for a combined kidney-pancreas transplant, provided that the candidate meets the criteria outlined in Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time).

~~Waiting time accrued by a combined kidney-pancreas candidate who has received a kidney-alone transplant may be assigned to a pancreas-alone and/or islet alone listing for that candidate.~~

A combined kidney-pancreas candidate who has received a kidney-alone transplant and is added to the pancreas-alone or pancreas islet waiting list will be assigned waiting time beginning on the earlier date of:

- The date the candidate was listed for a pancreas-alone transplant, or
- The date the candidate was listed for a combined kidney-pancreas transplant, or
- The date the candidate began accruing waiting time for a combined kidney-pancreas transplant.

**3.8.5.2 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates**

1. Waiting time accrued by a pancreas islet transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).
2. Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3. Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

**3.8.5.3 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 candidate 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 requiring the 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
  - A pancreatectomy operative report
- OR
- A completed Pancreas Waiting Time Reinstatement Form, and
  - A statement of intent from the transplant center to perform a pancreatectomy, and
  - A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

**3.8.6. Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased.** If a pancreas transplant candidate on the 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 candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify 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 candidate 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 Islet Allocation Protocol**

**3.8.7.1 Criteria for Active Status.** A candidate is not eligible for active status if the candidate:

- Is insulin independent and
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet<sup>SM</sup>.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, and
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet<sup>SM</sup> within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change.

If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months.

The transplant center must present any documentation required by this policy to the OPTN upon request.

**3.8.7.2 Accrual of Waiting Time.** 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.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate 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 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 or regional waiting list.

**3.8.7.3 Medical Suitability.** Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom

the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

**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,
- 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 his/her third islet infusion.

**Note: *The amendments to Policy 3.8 shall be implemented pending distribution to members and programming on UNet<sup>®</sup>. (Approved at the November 8-9, 2010 Board of Directors Meeting)***

***Because of the major substantive and formatting changes, only new content in the proposed policy language is underlined. Changes in location within Policy 3.8 are not denoted by underlines and strikethroughs.***

~~**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 candidate on the Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.7 and for whom there is a zero antigen mismatch with the donor. Within the Waiting List for isolated pancreas, candidates shall be prioritized as set forth in Policy 3.8.1.1 below. Within the Waiting Lists for kidney-pancreas combination and combined solid organ-islet transplant, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the 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 3.5.4. 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 candidate or pursuant to Policy 3.5.4 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/m<sup>2</sup>, shall be allocated regionally and then nationally, or for candidates 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/m<sup>2</sup> that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.5 below:~~

~~**3.8.1.1 Local 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 Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA)  $\geq$  80%)<sup>3</sup>; and~~
- ~~• All other isolated pancreas candidates.~~

~~**3.8.1.2 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 Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>3</sup>;~~
- ~~• All other 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 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~**3.8.1.3 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 Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>3</sup>;~~
- ~~• All other 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 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~**3.8.1.4 Facilitated Pancreas Allocation.** In the event that the 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~~

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<sup>3</sup> 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 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

~~retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates 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 Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%<sup>+</sup>; 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 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~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 Policy 3.8.1.7 in the event there is a candidate 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 in writing.~~

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~~**3.8.1.5 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/m<sup>2</sup> and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, 3.8.1.3, or 3.8.1.4, 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.~~

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~~If the donor is greater than 50 years old or has BMI greater than 30 kg/m<sup>2</sup>, 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.~~

~~**3.8.1.6 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. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are~~

~~medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.~~

~~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,~~
- ~~• 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.~~

### **Waiting Time**

~~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.~~

~~One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate 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 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 or regional waiting list.~~

### **Active and Inactive Status**

A candidate is ~~not~~ eligible for active status if the candidate:

- Is insulin independent ~~and~~
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet<sup>SM</sup>.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, ~~and~~
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet<sup>SM</sup> within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

### **Removal from the Waiting List**

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

~~**3.8.1.7 Mandatory Sharing of Zero Antigen Mismatch Pancreata.** In the event there is a candidate on the 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 Member for any highly sensitized candidate waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.4 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then be offered to the appropriate Member for any highly sensitized candidate (i.e. candidate with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>1</sup> 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 candidate listed on the Host OPO's local candidate waiting list for combined kidney/pancreas or isolated pancreas transplantation who~~

~~is mismatched with the donor and also has unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%. In this event, for local allocation, the pancreas shall be offered for the mismatched candidate(s) with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80% (based upon length of time waiting if more than one candidate meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally and nationally.~~

~~**3.8.1.7.1** **Organ Offer 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 UNet<sup>SM</sup> or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients<sup>4</sup> 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:~~

- ~~• allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, 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 10<sup>th</sup> 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<sup>SM</sup>, 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<sup>SM</sup>. No obligation to payback the pancreas 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.~~

~~**3.8.2** **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 candidate requires another organ or organ combination:~~

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

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<sup>4</sup> For the purposes of Policy 3.8.1.7.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

~~pancreas transplant if it is determined that the candidate requires a pancreas transplant.~~

- ~~(iii) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate is suitable for a pancreas-alone transplant.~~
- ~~(iv) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the candidate is suitable for a kidney-alone transplant.~~
- ~~(v) Waiting time accrued by an isolated pancreas transplant candidate while registered on the 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 Waiting List shall not be assigned to the listing for an isolated kidney transplant.~~

### **3.8.2.1 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates**

~~(i) Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~(ii) Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~**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 Waiting List.~~

~~**3.8.4 Reporting Candidates' Unacceptable Antigens.** To receive priority in the allocation of isolated pancreata based upon CPRA, candidate unacceptable antigens sufficient to yield CPRA  $\geq$  80%) must be entered into UNet<sup>SM</sup>—as described in Policies 3.8.1.1 – 3.8.1.4. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.~~

~~**3.8.5 Regional or National Allocation to Alternate Recipients.** For a pancreas that~~

~~is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.~~

### ~~3.8.6 Minimum Information for Pancreas Offers.~~

~~3.8.6.1 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 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; and~~
- ~~(xvi) HLAB, B, Bw4, Bw6, and DR antigens.~~

### ~~3.8.7 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased.~~

~~If a pancreas transplant candidate on the 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 candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify 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 candidate 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.~~

### ~~3.8.8 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 candidate 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 requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center~~

- ~~• A completed Pancreas Waiting Time Reinstatement Form, and~~
- ~~• A pancreatectomy operative report~~
- ~~OR~~
- ~~• A completed Pancreas Waiting Time Reinstatement Form, and~~

- ~~A statement of intent from the transplant center to perform a pancreatectomy, and~~
- ~~A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.~~

~~The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.~~

~~**3.8.9 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.~~