

### 3.0 ORGAN DISTRIBUTION

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

#### 3.2 UNOS PATIENT WAITING LIST. The following policies pertain to the UNOS Patient Waiting List.

##### 3.2.1 **Mandatory Listing of Potential Recipients.** All patients who are potential recipients of deceased organ transplants must be listed on the UNOS computer Waiting List.

3.2.1.1 **Prohibition of Listings by Non-Members.** Only UNOS Members will be permitted to have access to the UNOS Patient Waiting List. UNOS Members may not add waiting patients to the UNOS Patient Waiting List on behalf of transplant centers which are not members of UNOS.

3.2.1.2 **Prohibition of Access by Non-Members.** Only UNOS Members will be permitted to have access to the UNOS computer system (the "Match System"), which matches donors with waiting potential recipients for the purpose of organ allocation. UNOS Members shall neither allow non-members access to the Match System nor use the Match System on behalf of non-members.

3.2.1.3 **Prohibition for Non-Approved Programs.** No UNOS member shall add a patient to the UNOS Patient Waiting List for a transplant procedure for which the UNOS member has not received approved program status. Nor shall a UNOS member add another UNOS member's patient to the UNOS Patient Waiting List for a transplant procedure for which the other member has not received approved program status.

3.2.1.4 **Prohibition for Organ Offers to Non-Members.** UNOS Members shall not provide organs to non-member transplant centers except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs - Developmental Status).

3.2.1.5 **Renal and Renal-Pancreas Combination Patient Listing.** In order to list a potential recipient of a kidney or a kidney-pancreas combination transplant on the UNOS computer system waiting list, the potential recipient's complete HLA antigen information (at least 1 A, 1 B, and 1 DR antigen) must be included at the time of listing the potential recipient. This requirement shall not apply to potential recipients listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation. The entry of the complete HLA antigen information for patients on the UNOS Waiting List shall require the use of current World Health Organization (WHO) Nomenclature. (This requirement that WHO nomenclature be used shall be implemented with the implementation of the New UNOS Data Collection Forms.)

3.2.1.6 **Registration of In Utero Transplant Candidates.** Registration of an *in utero* transplant candidate on the UNOS Patient Waiting List is appropriate only when prenatal diagnostic tests confirm that the *in utero* candidate is viable and medically suitable to receive an organ transplant. The risk of associated complications becomes appropriately low at between 32 and 36 weeks gestation. An *in utero* transplant candidate shall be listed under a special status code on the UNOS Patient Waiting List.

3.2.1.7 **In Utero Waiting Time** If an *in utero* candidate is not assigned a thoracic organ transplant prior to delivery on the basis of Policy 3.2.1.6, the candidate's waiting time will recommence from the time of birth with the candidate listed under the regular status code.

3.2.1.8 **Waiting Time Modification.** Transplant candidates on the UNOS Patient Waiting List may have waiting time accrued under a previous waiting list registration reinstated under the following circumstances:

- i. The candidate was incorrectly removed from the UNOS Patient Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the waiting list.
- ii. The candidate was removed from the UNOS Patient Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the waiting list.

Upon receipt by the UNOS Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's UNOS computer history file, Organ Center staff may reinstate the candidate's waiting time.

All other requests for waiting time reinstatement that are not specified under OPTN/UNOS Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other OPTN/UNOS policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed, and then submitted to the appropriate OPTN/UNOS organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted to UNOS with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting) or Policy 3.5.12.1 (Time of Waiting) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the OPTN/UNOS Kidney & Pancreas Transplantation Committee, and in the case of requests for modifying waiting time for organs other than kidney and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Patients)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney & Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

- 3.2.1.8.1** Waiting Time Modification for Urgent Status Patients. Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates and Status 1A heart transplant candidates registered on the UNOS Patient Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the patient, or in renewing the patient's status. Supporting documentation must be submitted to UNOS, including a written request from the physician/surgeon in charge of the patient's care explaining the circumstance along with the appropriate status justification form and OPTN/UNOS Wait Time Modification Form. Upon receipt of completed documentation by UNOS, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.

***NOTE: The amendments to Policy 3.2.1.8 (Waiting Time Modification) shall be implemented following programming on the UNOS System.***

**3.2.1.9** Waiting Time Transferal. For the purpose of this policy, "primary waiting time" shall mean the longest time period a patient listed on the Patient Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A patient may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the patient as a transplant candidate by the New Primary Center. After receipt of a UNOS Wait Time Transfer Form, the date the patient first met waiting time criteria (the date from which primary waiting time will be calculated) at the New Primary Center will be modified in the computer system by the UNOS Organ Center as the date the patient met waiting time criteria at the Initial Primary Center. Subsequent to the receipt of this request, the patient is to be deleted from the Patient Waiting List of the Initial Primary Center. A notice of the primary waiting time transfer will be sent from the UNOS Organ Center to each of the centers involved.

*NOTE: New Policy 3.2.1.9 (Waiting Time Transferal) shall be implemented following programming on the UNOS System.*

**3.2.2** Multiple Listings Permitted. Patients may be listed on multiple transplant center local Waiting Lists. Each such multiple local listing may be added to the UNOS Patient Waiting List so that the same patient may be listed on the UNOS Waiting List multiple times. However, transplant centers may not list the same patient on more than one organ procurement organization's patient waiting list.

**3.2.2.1** Waiting Time Transferal for Multiple Listed Patients. For the purpose of this policy, "primary waiting time" shall mean the longest time period a patient listed on the UNOS Patient Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A patient may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the patient as a transplant candidate by the New Primary Center. After receipt of a Wait Time Transfer Form ~~written request from the patient which states the patient's intention to transfer his/her waiting time,~~ the date the patient's met waiting time criteria listing date (the date from which primary waiting time will be calculated) at the New Primary Center will be ~~entered~~ modified into the computer system by the UNOS Organ Center as the date the patient ~~was listed~~ met waiting time criteria at the Initial Primary Center. ~~This request must be signed by the patient, a legal guardian, or other individual having the power of attorney to act on the patient's behalf. Subsequent to the receipt of this request, the patient is to be deleted from the Waiting List of the Initial Primary Center as well as from the UNOS Patient Waiting List for the Initial Primary Center unless the patient elects to be listed at both centers. If the patient elects to be listed at both the New Primary Center and the Initial Primary Center, the~~ The patient will be assigned a new listing primary waiting time date in the UNOS Patient Waiting List computer record for the Initial Primary Center which corresponds with either the date on which the waiting time adjustment form is received by UNOS or the date on which the patient is listed at the New Primary Center, whichever is earlier. A ~~written~~ notice of the primary waiting time transfer will be sent from the UNOS Organ Center to each of the centers involved.

*The amendments to Policy 3.2.2.1 (Waiting Time Transferal for Multiple Listed Patients) shall be implemented following programming on the UNOS System.*

**3.2.2.2** UNet<sup>SM</sup> Indication of Multiple Listing. Transplant centers will be notified through UNet<sup>SM</sup> that patients are multiple listed, but will not be notified of the identities of other centers at which the patients are listed.

**3.2.2.3** UNet<sup>SM</sup> Notification of Transplantation or Death of Multiple Listed Patients.

Transplant centers will be notified through the UNet<sup>SM</sup> system when a multiple listed patient has been transplanted or reported as deceased by another center so that all other centers involved can investigate and request removal of the patient from the center's waiting list.

**3.2.2.4** Non-acceptance of Multiple Listing and/or Transferal of Primary Waiting Time. Every transplant program that does not accept multiple listed patients and/or does not allow these patients to transfer their primary waiting time to that center if the patient so desires, must fully inform the patient during the transplant evaluation process or sooner.

**3.2.3** Waiting Time Transferal and Multiple Listing. Every transplant program must inform every patient about the options of multiple listing, transferring primary waiting time, and the option to transfer their care to a different transplant center without loss of accrued waiting time, during the evaluation process, provide the patient with written material on these options, and maintain documentation that this requirement was fulfilled

*NOTE: New Policy 3.2.2.2 (UNet<sup>SM</sup> Indication of Multiple Listing), Policy 3.2.2.3 (UNet<sup>SM</sup> Notification of Transplantation or Death of Multiple Listed Patients), Policy 3.2.2.4 (Non-acceptance of Multiple Listing and/or Transferal of Primary Waiting Time), and Policy 3.2.3 (Waiting Time Transferal and Multiple Listing) shall be implemented following programming on the UNOS System.*

**3.2.34** Match System Access. OPOs are required to use the OPTN/UNOS Match System (UNet<sup>SM</sup> for the allocation of all deceased donor organs. ~~The allocation of any and all organs from deceased donors must be made through the UNOS Match System.~~ The Host OPO ~~or donor transplant center, as appropriate,~~ must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the UNOS Match System computer programs which determine organ allocation priorities. Such information must be entered into the UNOS Match System for all deceased donors. For all renal deceased donors, UNOS Members must enter all donor data into the UNOS Match System within 15 hours after organ recovery. The OPO shall be responsible for two separate determinations (e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from separate draws sent to the same lab) of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data in UNet<sup>SM</sup>. Each OPO shall establish and implement ~~an internal procedure for providing on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet<sup>SM</sup>.~~ The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Organs shall be allocated only to patients who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a patient who appears on a match run. For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a patient who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific patient. If an organ is declined for a patient, a notation of the reason for the decision refusing the organ for that patient must be made on the appropriate OPTN form and promptly submitted.

*NOTE: The bolded amendments to Policy 3.2.4 (Match System Access) shall be implemented following programming*

*on the UNOS System.-(Implemented June 29, 2004)*

*NOTE: All other amendments(non-bolded) shall be effective October 4, 2004.*

**3.2.34.1** Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased. If a kidney, kidney/pancreas or kidney/islet 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 organ waiting lists for that transplanted organ and shall notify UNOS within 24 hours of the event. If the recipient is again added to a waiting list for that transplanted organ, waiting time shall begin as of the date and time the patient is relisted. If the recipient is waiting for a combined kidney/pancreas or kidney/islet transplant and receives only an isolated kidney transplant, the recipient's accrued kidney waiting time shall automatically be transferred to the isolated pancreas or islet, as applicable, Waiting List.

**3.2.34.2** 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 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: (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 patient 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 patient'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. UNOS will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

**3.2.4.5** Preliminary Stratification. The acceptable donor size must be specified for every potential liver recipient on the UNOS Patient Waiting List.

**3.2.56** Waiting Time for Patients in an Inactive Status. Unless otherwise stipulated in each organ specific allocation policy, waiting time beyond 30 days shall not be accrued by patients while they are registered on the UNOS Patient Waiting List as being inactive.

**3.2.67** Pancreas Waiting List Criteria. Each candidate registered on the UNOS pancreas waiting list must be diagnosed as a diabetic or have pancreatic deficiency.

**3.2.7** Combined Kidney-Pancreas Waiting List Criteria. Each candidate registered on the UNOS kidney-pancreas waiting list must be diagnosed as a diabetic or have pancreatic deficiency with renal insufficiency.

**3.2.89** Waiting Time Adjustment for Patients Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises. Waiting time accrued by a patient for a transplant of a life-saving organ while waiting on the UNOS Patient Waiting List may also be accrued for a second organ, when it is determined that the patient requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.