3.0 ORGAN DISTRIBUTION

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

3.1 DEFINITIONS.

The following terms are defined as having the following meanings for the purposes of UNOS policy:

3.1.1 OPO. An Organ Procurement Organization (OPO) is an organization, accepted as a member of UNOS, and authorized by the Health Care Financing Administration (HCFA) to procure organs for transplantation. For each OPO, HCFA defines a geographic procurement territory within which the OPO concentrates its procurement efforts. No OPO is limited to or granted exclusive procurement rights to procure organs in its territory.

3.1.2 Transplant Center. A transplant center is a hospital that is a member of UNOS in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's patient to ensure medical suitability of donor organs for transplantation into the potential recipient, including ~~for example,~~ compatibility of donor and patient by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying ~~performing a crosscheck verification of~~ the recorded donor~~'s~~ ABO with the recorded ABO of the intended recipient. This action must be documented and is subject to review upon audit.

NOTE: The amendment to Policy 3.1.2 (Transplant Center) shall be implemented following programming on the UNOS System. (Implemented June 29, 2004)

3.1.3 Transplant Program. A transplant center, or hospital, may have one or more transplant programs. Each program oversees transplantation of one or more organ types.

3.1.4 UNOS Patient Waiting List. The UNOS Patient Waiting List is the computerized list of patients who are waiting to be matched with specific donor organs in hopes of receiving transplants. Waiting List patients are registered on the UNOS Patient Waiting List by UNOS member transplant centers~~, programs, or OPOs~~. **The candidate's transplant program shall be responsible for ensuring the accuracy of candidate ABO data on the waiting list. Each transplant program shall implement and operate ~~an internal~~ procedure for providing on-line verification of a candidate's ABO data on the waiting list** against the source document **by an individual other than the person initially entering the candidate's ABO data in UNet[sm]. The transplant program shall maintain records documenting that such separate verification** of the source document against the entered ABO **has taken place and make such documentation available for audit. Upon entry of the candidate's waitlist data, the candidate will be added to the waitlist but will not be listed as an active candidate until separate verification of the candidate's ABO data has taken place.**

NOTE: The bolded amendments to Policy 3.1.4 (UNOS Patient Waiting List) shall be(Implemented June 29, 2004) .
NOTE: The unbolded amendments to Policy 3.1.4 (UNOS Patient Waiting List) shall be effective October 4, 2004.

3.1.4.1 All transplant candidate interactions will be required to be completed through UNet[sm] by transplant programs. The Organ Center will facilitate patient listings and modifications in the event of computer and/or Internet failure. When the Organ Center facilitates a patient's listing or modification due to computer and/or Internet failure, the transplant center will be required to submit a statement explaining the event.

3.1.4.2 Each transplant candidate must be ABO typed on two separate occasions prior to

listing.

3.1.4.3 Transplant candidates shall only be listed on the UNOS computer system with the candidate's actual blood type.

NOTE: New policies 3.1.4.1, 3.1.4.2, and 3.1.4.3 shall be effective October 4, 2004.

3.1.5 UNOS Match System. The UNOS Match System is the computerized algorithm used to prioritize patients waiting for organs. It eliminates potential recipients whose size or ABO type is incompatible with that of a donor and then ranks those remaining potential recipients according to the ranking system approved by the UNOS Board.

3.1.6 Host OPO. The Host OPO is the OPO which, having identified a potential organ donor, assumes responsibility for donor management and organ allocation.

3.1.7 Local and Alternative Local Unit. The Local Unit will be the OPO in most cases. Alternative Local Units (Alternative Local Units or ALUs) such as subdivisions of the OPO which function as distinct areas for organ procurement and distribution, entire states, UNOS regions or other appropriate units are acceptable if they can be demonstrated to the satisfaction of the UNOS Board of Directors to fulfill the principles below and adhere to applicable laws and regulations.

The principles for defining local, all of which should be addressed and appropriately balanced in each instance, are as follows:

3.1.7.1 There should be a single waiting list for each organ within each Local Unit. Any deviation from this principle must be submitted to UNOS for approval.

3.1.7.2 There should be Local Unit review. The OPO or OPOs involved shall collect and review data on organ procurement, organ distribution, organ quality, and organ function for the Local Unit.

3.1.7.3 There should be a demonstrated inequity in organ distribution within the OPO or OPOs involved that is addressed by the ALU and corrected or at least improved within a specified period of years as shown through objective criteria. The purpose of the ALU should be to provide a system of equitable organ distribution. Equitable organ distribution should attempt to balance justice and medical utility.

3.1.7.4 There should be monitorable organ distribution. Data collection and review are necessary to be certain that the distribution system is being followed and that it is achieving its goals.

3.1.7.5 There should be no organ distribution predicated on the procuring transplant center or individual.

3.1.7.6 There should be effective organ procurement throughout the Local Unit. Enhancement of the organ supply should be a primary goal of any organ distribution system.

In cases where a subdivision of an OPO is the Local Unit, organs recovered, but not used within that segment of the OPO will be used in the remainder of the OPO before regional or national distribution. It is the policy of UNOS to encourage cooperative working relationships within and among OPOs to serve the best interests of transplant patients, in a manner that is consistent with the principles set forth in the Policy 3.1.7.

3.1.8 Sharing Arrangement and Sharing Agreement. The term sharing arrangement refers to an arrangement entered into by two or more OPOs to share organs, interregionally or

intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement with the prior approval by the UNOS Board of Directors. Organs must be distributed within the sharing area on the basis of a common Patient Waiting List unless an appropriate Alternative Local Unit for the area is approved by UNOS. With the exception of arrangements that are approved for a finite time period to test a stated hypothesis with defined parameters under controlled conditions, OPOs participating in a sharing arrangement must have geographically contiguous service areas. The term sharing agreement refers to the written document that defines the sharing arrangement.

3.1.9 **Alternate Point Assignment (Variances).** An OPO, UNOS Members participating in a UNOS approved Alternative Local Unit or UNOS Members participating in a UNOS approved sharing arrangement may assign to each of the point system criteria set forth in Policies 3.5 through 3.11 a number of points other than the number of points set forth in such policies for allocation of local organs with the prior approval by the UNOS Board of Directors. UNOS Members participating in an approved alternate point system (variance) shall be obligated to: (a) stay aware of all applicable provisions of the UNOS organ allocation policies and any amendments thereto ("policy requirements") (as well as all other UNOS By-Laws and Policies), (b) evaluate the continued benefit of the alternate point system in light of the policy requirements and (c) request UNOS Committee and Board of Director approval for any adjustment to the alternate point system deemed appropriate and desirable by the Member(s) following such evaluation. No UNOS approved alternate point system will automatically be modified in light of or to incorporate in any way any policy requirement adopted by the UNOS Board of Directors following approval of the alternate point system unless otherwise specifically provided by the Board of Directors. Any modification of an approved alternate point system shall require application by the applicable UNOS Member(s) in accordance with Policy 3.4.6.4.

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 int~~o~~ 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[SM] Indication of Multiple Listing. Transplant centers will be notified through UNet[SM] 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[SM] Notification of Transplantation or Death of Multiple Listed Patients. Transplant centers will be notified through the UNet[SM] 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[SM] Indication of Multiple Listing), Policy 3.2.2.3 (UNet[SM] 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.

3.2.3~~4~~4 Match System Access. OPOs are required to use the OPTN/UNOS Match System (UNet[SM] 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[SM]. 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[SM]. 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.~~3~~4.1 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.~~3~~4.2 Waiting Time Reinstatement for Kidney Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor kidney, the 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.~~5~~6 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.~~6~~7 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.~~8~~9 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.

3.3 ACCEPTANCE CRITERIA. The following policies apply to donor and organ acceptance criteria:

3.3.1 Donor Acceptance Criteria. Each organ procurement organization shall establish criteria defining what constitutes an acceptable deceased donor or organ for the OPO or the transplant program(s) it serves. Each OPO is required to offer organs to OPOs with more liberal criteria when, as the Host OPO, it chooses to reject a particular deceased donor.

3.3.2 Non-renal Organ Acceptance Criteria. A transplant center may inform the UNOS Organ Center of the criteria according to which that transplant center will accept non-renal organs allocated through the UNOS Organ Center. The UNOS Organ Center will not subsequently offer that transplant center non-renal organs that fail to meet such criteria.

3.3.3 Renal Acceptance Criteria. All transplant centers must inform the UNOS Organ Center of the criteria according to which they will accept deceased kidneys allocated through the UNOS Organ Center. The UNOS Organ Center will not subsequently offer to that transplant center deceased kidneys that fail to meet the center's acceptance criteria.

3.3.4 Antigen Mismatch Criteria. A transplant center may specify the maximum number of mismatched antigens acceptable for any of its patients. The UNOS computer Match System will then print only those patients with a number of antigens mismatched with a donor equal to or less than such maximum mismatch criteria.

3.3.5 Transplant Recipient Backup for Organ Offers. OPOs are encouraged to make backup offers for all organs. A backup offer shall be considered equivalent to an actual organ offer and the backup center shall have one hour to respond after receiving the minimum data required for an organ offer pursuant to UNOS Policies 3.5.7, 3.6.9, 3.7.9 and/or 3.8.5. Refusal to consider or respond to a backup offer will be considered as a refusal to accept the organ. The backup center may later refuse to accept the organ based on medical or logistical criteria. The backup center should be notified promptly of any change in donor status or

organ disposition.

3.3.6 **Center Acceptance of Organ Offers.** If an organ is offered and accepted without conditions, the Host OPO and recipient transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION. The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

3.4.1 **Time Limit For Acceptance**. Once the appropriate donor information is provided as described in Policies 3.5.7, 3.6.9, 3.7.9, and 3.8.5 a transplant center shall be allowed one hour from the time of the organ offer, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and 3.8.1.6.1 (Time Limit), in which to communicate its acceptance of the organ. After one hour, or shorter period as defined under Policies 3.3.5 and 3.8.1.6.1, the offering entity may offer the organ to the transplant center for the patient listed next in priority by the UNOS Match System.

3.4.2 **Multiple Organ Retrieval**. After a UNOS member indicates its initial acceptance of an organ, the transplant centers or OPOs involved must agree upon the time that multiple organ procurement will begin. If the procurement time cannot be agreed upon, the Host OPO may withdraw the offer from the transplant center or OPO unable to agree upon a time for procurement to begin.

3.4.3 **Department of Defense Directive.** Until such time as UNOS and the Department of Defense (DOD) reach a mutual understanding on organ allocation policies, UNOS Members may cooperate with U.S. military facilities that are bound by DOD organ allocation directives which are in conflict with UNOS policies. However, UNOS neither agrees with nor endorses present DOD directives.

3.4.4 **Multiple Organs Offer.** If an OPO has permission to procure all organs from a particular donor, that OPO shall offer those organs through the UNOS Match System unless there is a contraindication to organ procurement.

3.4.5 **National Distribution of Organs.** After an organ has been unsuccessfully offered to appropriate UNOS Members for allocation to local patients or unsuccessfully offered to UNOS Members through an approved regional sharing arrangement, the UNOS Organ Center will allocate an abdominal organ first regionally, and then nationally, based upon the point system set forth in UNOS policies. The UNOS Organ Center will allocate thoracic organs according to Policy 3.7.

3.4.6 **Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified alternative organ distribution or allocation system, review of such systems by UNOS and withdrawal from such systems by any one or more the participants.

3.4.6.1 Application. Applications to allocate organs locally using alternate point assignments (variances) may be submitted by OPOs, UNOS Members participating in a UNOS approved ALU or UNOS Members participating in a UNOS approved sharing arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the variance whether or not the institution supports the variance. Applications to distribute organs according to sharing arrangements or ALUs may be submitted by OPOs; any such application must indicate for each applicant OPO whether or not the OPO's Board of Directors

supports the sharing arrangement or ALU, as applicable. In cases where unanimity cannot be achieved at the local level, applications to allocate organs using either a variance, sharing agreement or ALU must have approval of 75% of the UNOS member OPOs and or transplant centers.

Applications to allocate organs using alternate point assignments (variances) or to distribute organs using sharing arrangements or ALUs must be considered by the applicable UNOS Region(s) and by the appropriate UNOS organ-specific committees and Board of Directors. The Board of Directors may refer any such application to additional UNOS reviewing committees as deemed appropriate by the Board. Regional consideration of applications must occur prior to their submission to the Board of Directors and shall include a non-binding vote by the institutional UNOS Membership within the applicable region; this vote and any commentary shall be submitted to the appropriate UNOS committees and Board of Directors for use in their respective deliberations of the application. Applications to distribute organs using an ALU must demonstrate an inequity in organ distribution within the applicable OPO or OPOs and how this inequity is corrected by the ALU without disproportionate harm to any patient population within the local area. The application must, at a minimum, address the following criteria, and how they are expected to be impacted by the ALU: (a) patient waiting time (stratified by patient populations), (b) graft survival (stratified by patient populations), and (c) organ availability.

Applications shall address the considerations stated in Section 121.8 (a) and (g) of the Final Rule and must comply with other application requirements as may be established by the appropriate UNOS committees and Board of Directors. All alternate point assignments (variances), sharing arrangements and ALUs must be approved by the UNOS Board of Directors and programmed on the UNOS computer prior to implementation. In the case of ALUs, initial approval by the Board of Directors shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable OPO(s) must have demonstrated through objective criteria that the inequity addressed by the ALU has been corrected or at least that improvement to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the ALU be: (a) finally approved, (b) approved on a continued provisional basis for a specific period of time, or (c) terminated.

When a variance, sharing arrangement or ALU is proposed to permit participation of a distribution unit in a scientific study to test a stated hypothesis with defined parameters under controlled conditions, such a variance, sharing arrangement or ALU may be approved by the Board of Directors for implementation if it (a) is of scientific merit (The Board may consider prior approval of such national agencies as the National Institutes of Health, Veterans Administration or national voluntary health agencies in making this determination); (b) extends for a defined, limited time period not greater than 5 years; and, (c) will have no net effect on the number of organs available for transplant within the applicable distribution unit, or potentially affected larger distribution units which include the applicable distribution unit. Such proposals will be considered in accordance with the standard UNOS process for consideration of variances, sharing arrangements or ALUs, as applicable.

3.4.6.2 Data Submission Requirements. UNOS Members receiving permission of the UNOS Board of Directors for evaluating alternate point assignments (variances), sharing arrangements and ALUs, including those denied with conditions and those approved on a provisional basis, shall submit to UNOS, at one-year intervals, or more frequently upon request, relevant data and status reports that assess the impact of the alternative system, address any organ allocation problems that may have arisen as a result of the system and, in the case of ALUs, demonstrate adherence to

the principles for defining local (Policy 3.1.7) and progress toward correcting or at least reducing the inequity that the ALU is intended to address, using, at a minimum, the criteria of patient waiting time, graft survival, and organ availability. From time to time, UNOS may provide these Members with data reports (from the UNOS database) showing the experience of the alternative organ distribution\allocation system as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. UNOS Members receiving approval by the Board of Directors to participate in a variance, sharing arrangement or ALU as part of a limited duration scientific study shall be subject to the data submission requirements stipulated above in addition to submission of a final report within six months following completion of the study.

The appropriate UNOS committee(s) shall actively monitor these data and status reports to provide consistency to UNOS' efforts to assist the participating OPOs and transplant centers in dealing with each of their special circumstances; to make recommendations to the UNOS Board of Directors for continuation, modification or termination of the alternate systems; and, in the case of variances, to review the alternative system in light of standard UNOS organ allocation policies. This provision shall not be interpreted to limit or otherwise affect UNOS' authority to revoke or suspend operation of any alternative organ distribution or allocation system as deemed appropriate by the UNOS Board of Directors.

3.4.6.3 Dissolution of Alternate Point Assignments (Variances), Sharing Arrangements and ALUs. UNOS Members operating with an approved (a) alternate point system (variance) who unanimously elect to withdraw from that system and use the standard point system criteria pursuant to UNOS Policies 3.5 through 3.11, (b) sharing arrangement who unanimously elect to withdraw from that arrangement and define the OPOs as the Local Units for purposes of organ distribution or (c) ALU who unanimously elect to withdraw from that ALU and use the OPO, or larger sharing area under a UNOS-approved sharing arrangement, as the Local Unit pursuant to Policy 3.1.7, shall provide timely written notification of such withdrawal and resulting dissolution of the variance, sharing arrangement or ALU, as applicable, to the relevant UNOS region, appropriate UNOS committees and the Board of Directors. Dissolution of the variance, sharing arrangement or ALU, as applicable, shall be effective after appropriate re-programming of the UNOS computer. A request to withdraw from a variance, sharing arrangement or ALU that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.6.4 below.

3.4.6.4 Modifications of Alternate Point Assignments (Variances), Sharing Arrangements and ALUs. Any proposed modification of an approved variance, sharing arrangement or ALU, other than a proposal to dissolve the system agreed to unanimously by the parties, shall require application by the participating UNOS Member(s) in the case of a variance, or participating OPOs in the case of a sharing arrangement or ALU, and approval by UNOS in accordance with the application process described in Policy 3.4.6.1 above.

3.4.6.5 ALUs Approved Prior to February 1, 1999. If as of February 1, 1999, an OPO or OPOs are using a UNOS approved ALU that meets the criteria for an ALU in effect prior to that date, such an ALU must be evaluated within 3 years of February 1, 1999 in accordance with the principles set forth in this Policy 3.4.6, but may remain in effect until that review.

3.4.7 Allocation of Organs During Regional/National Emergency Situations. In the event of a regional or national emergency situation that compromises telecommunications,

transportation, or the function of / access to the OPTN waiting list and organ matching system, a notice and instructions will be distributed, if possible, to all OPTN transplant centers and organ procurement organizations advising them of the impact of the situation on the OPTN system and how members should proceed with organ allocation, distribution and transplantation. OPTN members should reference Policies 3.4.7.1; 3.4.7.2; and 3.4.7.3 in cases of regional/national emergency.

3.4.7.1 Regional/National Transportation Disruption. In these situations, the OPTN and members are able to communicate and the waitlist and matching systems are accessible, but transportation of organs is either not possible or severely impaired. Members are required to contact the OPTN to determine proper operating procedures.

3.4.7.2 Regional/National Communications Disruption. In these situations, the OPTN and members are unable to communicate through one or more of the available communications methods (internet and phones) and the waitlist and matching system are operational.

Internet Outage. Members are required to contact the OPTN and determine the proper operating procedures.

Telecommunications (Land and Mobile Phone) Outage. Internet contact with the OPTN should be made via e-mail to determine operation procedures and to obtain assistance. Members will continue to use the waitlist and matching system for organ allocation and distribution. Organ procurement organizations must document any variations in allocation or distribution due to telecommunications problems for submission to the Policy Compliance Department.

Combined Outage. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not accessible. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the Policy Compliance Department.

3.4.7.3 OPTN Operational Disruption. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not operational. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the Policy Compliance Department.

NOTE: New Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations) shall be effective June 25, 2004.

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

submitted promptly to UNOS.

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

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

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

X=Expanded Criteria Donor
CVA=CVA was cause of death
HTN=history of hypertension at any time
Creat > 1.5 = creatinine > 1.5 mg/dl

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

3.5.3 **Mandatory Sharing of Zero Antigen Mismatched Kidneys.** The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a patient on the UNOS Patient Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a patient on the UNOS Waiting List has an ABO blood type that is compatible with that of the donor and the patient 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 patient each has the same antigens identified at each pair of A, B, and DR HLA loci. Patients 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 patient 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 patient but the donor is typed as being homozygous for one of the patient's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into the UNOS computer system prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any patient on the UNOS Patient Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to patient waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to UNOS.

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

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional

points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

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

NOTE: The amendment to Policy 3.5.3.3 (Mandatory Sharing) shall be implemented pending programming on the UNOS system.

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

i local patients; then to
ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii 80% or higher PRA patients on the regional waiting list; then to
iv 80% or higher PRA patients on the national waiting list; then to
v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to
vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to
viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix 21%-79% PRA patients on the regional waiting list; then to
x 21%-79% PRA patients on the national waiting list; then to
xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
xiii less than or equal to 20% PRA patients on the national waiting

list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched patients, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and, then, to blood type A and AB zero antigen mismatched patients, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all compatible blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)– (viii) below:

i local patients; then to
ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii 80% or higher PRA patients on the regional waiting list; then to
iv 80% or higher PRA patients on the national waiting list; then to
v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to
vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to
viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
ix 21%-79% PRA patients on the regional waiting list; then to
x 21%-79% PRA patients on the national waiting list; then to
xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiv less than or equal to 20% PRA patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not

meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt), ranked by OPO in inverse order of the highest number of payback obligations owed by the OPO if more than one OPO is in this category.

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

3.5.3.5 Time Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through the UNOS Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). The UNOS Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated kidney 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 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally). The period of time allowed for acceptance of zero antigen mismatched standard kidney 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 standard zero mismatched donor kidneys. In the event the Host OPO declines the opportunity to allocate standard donor 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 3.5.5 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for expanded criteria donor kidney transplantation for a period of two 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 3.5.6 (first locally, then regionally, and then nationally) for patients designated as eligible to receive expanded criteria donor kidneys. The period of time allowed for acceptance of zero antigen mismatched expanded criteria donor kidney offers made within the two hours permitted for placing these organs, but with less than an hour before the two hours will expire, shall equal the time remaining within the two-hour period for placement of expanded criteria zero mismatched donor kidneys. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. The UNOS Organ Center will document each offer and each response.

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-

pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.

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

3.5.5 **Payback Requirements**. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), ~~and~~ 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor[1], six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

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

NOTE: The amendment to Policy 3.5 (Payback Requirements) shall be implemented pending programming on the UNOS system.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

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

3.5.5.1.2

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

NOTE: The amendments to Policy 3.5.5.1.1 (Deferment of the Kidney/Non-Renal Exception) and Policy 3.5.5.1.2 (Deferment of Voluntary Arrangements) shall be implemented pending programming on the UNOS System.

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

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

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

3.5.6.1 Local Allocation. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to local patients as defined in Policy 3.1.7 the locale where the kidneys are procured.

3.5.6.2 Regional Allocation. If a standard donor kidney is not accepted by any of the local transplant centers for local patients, the kidney is to be allocated next via the regional list consisting of all patients listed on the Waiting Lists of other UNOS Members within the same UNOS region as the UNOS member which procured the kidney. When a standard donor kidney is allocated regionally, it is to be offered to UNOS Members for specific patients in the region according to the point system described in Policy 3.5.11 in descending point order beginning with the patient in the region who has been assigned the highest number of points. With all regionally-shared standard donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the patient. Selection of alternate patients must be according to the UNOS point system for standard kidney allocation. If a local potential recipient(s) who has agreed to receive expanded

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

3.5.6.3 National Allocation. If a standard donor kidney is not accepted by any transplant center in the UNOS region in which the UNOS member which procured the kidney is located, the kidney is to be allocated to UNOS Members for specific patients in the other UNOS regions nationally according to the point system described in Policy 3.5.11 in descending point order beginning with the patient who has the highest number of points. With all nationally shared standard donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that patient. Selection of alternate patients must be according to the UNOS point system for standard donor kidney allocation. If an expanded criteria donor kidney is not accepted by any transplant center in the UNOS region in which the UNOS member which procured the kidney is located, the kidney is to be allocated to UNOS Members for specific patients who have agreed to receive expanded criteria donor kidneys in the other UNOS regions nationally according to the point system described in Policy 3.5. 12 in descending point order beginning with the patient who has the highest number of points. With all nationally shared expanded criteria donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that patient. Selection of alternate patients must be according to the UNOS point system for expanded criteria donor kidney allocation.

3.5.6.4 UNOS Regions. UNOS Members belong to the UNOS region in which they are located. The UNOS regions are as follows:

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

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

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

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

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

3.5.9 **Minimum Information/Tissue for Kidney Offer.** The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and OPTN Donor I.D. number, age, sex, and race;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;
(v) HLA typing;
(vi) Current history of abdominal injuries and operations;
(vii) Pertinent past medical or social history;
(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
(ix) Final urinalysis;
(x) Final BUN and creatinine;
(xi) Indications of sepsis;
(xii) Assurance that final blood and urine cultures are pending;
(xiii) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
(xiv) Current medication and transfusion history;
(xv) Recovery blood pressure and urine output information;
(xvi) Recovery medications;
(xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
(xviii) Description of typing material available, including, as a minimum for each kidney:
- One 7 to 10ml. clot (red topped) tubes, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available

(xix) Warm ischemia time and organ flush characteristics; and
(xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood vessels, ureter(s) or kidney.

3.5.10 **Preservation Mode of Shared Kidneys.** Unless agreed upon in advance by the Host OPO and recipient center, a recipient center shall not change the preservation mode until the final

crossmatch is complete and it is certain that the recipient center will use the kidney.

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

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on the UNOS Computer; provided, however, that "time of waiting" under this policy shall not precede the date of the patient's listing. Programs must be able to verify with appropriate supporting documentation~~, supplementing the Waiting Time Qualification Form referred to below,~~ that the patient met the criteria as of the date submitted; this documentation will be subject to audit by UNOS either through on site audits or otherwise upon request for submission to UNOS. Programs shall enter information required by the Waiting Time Qualification Form on the UNOS Computer, including whether the patient met the following criteria~~A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the Computer~~:

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

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

NOTE: The amendment to Policy 3.5.11.1 (Time of Waiting) shall be implemented pending programming on the UNOS System. (Implemented June 29, 2004)

3.5.11.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the patient waiting for the longest period with fractions of points being assigned proportionately to all other patients, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a patient accrues, an additional 1 point will be assigned to that patient. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney 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 and regional lists.

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a patient based on the number of mismatches between the patient's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be

recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

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

UNOS HLA Mismatch Definitions*

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

- Antigens that UNOS considers to be equivalent for matching purposes are currently shown in Appendix C of the UNOS Computer User's Manual.

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

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

3.5.11.3 Panel Reactive Antibody. A patient will be assigned 4 points if he or she has panel reactive antibody (PRA) level of 80% or greater based upon 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. For geographic allocation units with UNOS approved renal allocation variances that assign points for PRA level, PRA points will also be assigned based on the historic or current serum sample as used for crossmatch to determine crossmatch suitability.

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

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant

candidates who are less than 11 years old shall be assigned four additional points for kidney allocation. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for kidney allocation. These points shall be assigned when the candidate is registered on the UNOS Patient Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals. Kidneys that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing and who have not received a kidney transplant within the time periods set forth in Policy 3.5.11.5.2 irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed patients based upon total points assigned under UNOS policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these patients in descending point sequence with the patient having the highest number of points receiving the highest priority. The priority assigned for pediatric patients under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) ~~or in satisfaction of payback debts pursuant to Policy 3.5.5 (Payback Requirements)~~.

NOTE: The amendment to Policy 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) shall be implemented pending programming on the UNOS System.

3.5.11.5.2 Pediatric Goals for Transplanting Kidney Transplant Candidates. The goals for transplanting pediatric kidney transplant candidates are as follows:

(a) Candidates 0-5 years old at time of listing- within 6 months of listing.

(b) Candidates 6-10 years old at time of listing- within 12 months of listing.

(c) Candidates 11-17 years old at time of listing- within 18 months of listing.

3.5.11.6 Donation Status. A patient will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the patient's physician must provide UNOS with the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other patient information required to be submitted under UNOS policy. Additionally, at the local level of organ distribution only, patients assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these patients according to length of time waiting.

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

3.5.12.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on the UNOS Computer; provided, however, that "time of waiting" under this policy shall not precede the date of the patient's listing. Programs must be able to verify with appropriate supporting documentation~~, supplementing the Waiting Time Qualification Form referred to below,~~ that the patient met the criteria as of the date submitted; this documentation will be subject to audit by UNOS either through on site audits or otherwise upon request for submission to UNOS. Programs shall enter information required by the Waiting Time Qualification Form on the UNOS Computer, including whether the patient met the following criteria~~A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the Computer~~:

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

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

NOTE: The amendments to Policy 3.5.12.1 (Time of Waiting) shall be implemented pending programming on the UNOS System. (Implemented June 29, 2004)

3.5.12.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the patient waiting for the longest period with fractions of points being assigned proportionately to all other patients, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a patient accrues, an additional 1 point will be assigned to that patient. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney 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 and regional lists.

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

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

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

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

3.5.17 **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 3.5.17 (Prospective Crossmatching) shall be effective January 1, 2005.

3.6 **ALLOCATION OF LIVERS.** Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgement for the benefit of liver transplant candidates as a group, each patient will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Patients will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

Livers will be offered to patients with an assigned Status of 1 in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in other categories within distribution areas as noted below. Following Status 1, livers will be offered to patients based upon their probability of candidate death derived from assigned MELD or PELD scores, as applicable, in descending point sequence with the patient having the highest probability ranking receiving the highest priority before being offered to patients having lower probability rankings.

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old*)* will be allocated in the following sequence *(*adult donor liver allocation algorithm*)*:

Adult Donor Liver Allocation Algorithm

Local

1. Status 1 patients in descending point order

Regional

2. Status 1 patients in descending point order

~~**Local**~~

~~3. All other patients in descending order of mortality risk scores (probability of candidate death)~~

~~**Regional**~~

~~4. All other patients in descending order of mortality risk scores (probability of candidate death)~~

Local

3. Patients with MELD/PELD Scores >=15 in descending order of mortality risk scores (probability of candidate death)

Regional

4. Patients with MELD/PELD Scores >=15 in descending order of mortality risk scores (probability of candidate death)

Local

5. Patients with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

6. Patients with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

7. Status 1 patients in descending point order

~~5. All other patients in descending order of mortality risk scores (probability of candidate death)~~

8. All other patients in descending order of mortality risk scores (probability of candidate death)

NOTE: The amendments to Policy 3.6 (Adult Donor Liver Allocation) shall be implemented pending programming on the UNOS system.

Within liver Status 1 and the organ distribution system defined in this policy for adult donor livers, a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate (according to the pediatric donor liver allocation algorithm set forth below); provided, however, that the recipient transplant program cannot use only part of the liver in a single patient without offering the remaining portion(s) for transplantation:

(i) in sequence, as determined by the adult donor liver allocation algorithm set forth above and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or

(ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

In the event that the transplant program receiving the liver offer declines to transplant the whole organ into the designated candidate or to transplant a part of the organ into the designated candidate, offering the remaining portion(s) for transplantation as described earlier in this paragraph, then the donor liver shall be allocated to the next candidate on the waiting list, in the sequence outlined below (i.e., the pediatric donor liver allocation algorithm). For purpose of Policy 3.6, pediatric patients and organ donors are defined as less than 18 years of age.

Pediatric Donor Liver Allocation Algorithm

Local

1. Pediatric Status 1 patients in descending point order
2. Adult Status 1 patients in descending point order

Regional

3. Pediatric Status 1 patients in descending point order
4. Adult Status 1 patients in descending point order

Local

5. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
6. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
7. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
8. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

Regional

9. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
10. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
11. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
12. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

National

13. Pediatric Status 1 patients in descending point order
14. Adult Status 1 patients in descending point order
15. All other pediatric patients with a PELD score or MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
16. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
17. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
18. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

The liver must be transplanted into the original designee or be released back to the Host OPO or to the

UNOS Organ Center for distribution. If a liver is offered to a patient who is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the liver is being distributed, then the liver shall be released back to the Host OPO or to the UNOS Organ Center for allocation to other liver transplant candidates in accordance with UNOS Policy 3.6. The final decision whether to use the liver 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 judgement about the suitability of the liver being offered for their specific patient; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If a liver is declined for a patient, a notation of the reason for the decision not to accept the liver for that patient must be made on the appropriate UNOS form and promptly submitted to UNOS.

Allocation Sequence for Patients with PELD or MELD Scores Less Than or Equal to 6 (All Donor Livers).

Adult patients and pediatric adolescent patients with a MELD score of 6 will be considered together with ~~all~~ pediatric patients ≤12 years with a PELD score less than or equal to 6. These patients will be initially ranked based upon waiting time. Those waiting list positions assigned to pediatric candidates based on this initial ranking (e.g., if the 3rd and 5th on the ranked list are held by pediatric patients) will then be re-distributed amongst the pediatric group based on PELD or MELD score, with the patient with the highest PELD or MELD, as applicable score receiving the highest available pediatric ranking position. The next available pediatric ranking position will be assigned to the pediatric candidate with the next highest PELD or MELD score. Re-distribution of pediatric candidates continues until the pediatric candidate with the lowest PELD or MELD score is assigned the last pediatric ranking position.

NOTE: The amendments to Policy 3.6. (Allocation of Livers) shall be implemented pending programming on the UNOS System.

3.6.1 **Preliminary Stratification**. For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The UNOS Match System will consider only potential liver recipients who are an acceptable size for that particular donor liver.

3.6.2 **Blood Type Similarity Stratification/Points.** For Status 1 transplant candidates, patients with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from ~~an~~ a ~~A_2~~ non-A_1 blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

NOTE: The amendments to Policy 3.6.2 (Blood Similarity Stratification/Points) shall be implemented following programming on the UNOS System.

3.6.2.1 **Allocation of Blood Type O Donors**. With the Exception of Status 1 patients, blood type O donors may only be allocated to blood type O patients, or B patients with a MELD or PELD score greater than or equal to ~~**20**~~ **30**. Any remaining blood type compatible candidates will appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level.

NOTE: The amendments to Policy 3.6.2.1 (Allocation of Blood Type O Donors) shall be implemented following programming on the UNOS System.

3.6.2.2 **Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type.** For Status 1 candidates, or candidates with a MELD or PELD score of 25 and

greater, centers may specify on the waiting list those patients who will accept a liver from a donor of any blood type.

3.6.3 **Time Waiting**. Transplant candidates on the UNOS patient waiting list shall accrue waiting time within Status 1 or any assigned MELD or PELD score; however, waiting time accrued while listed at a lower MELD/PELD score will not be counted toward liver allocation if the patient is upgraded to a higher MELD/PELD score. Stratification of patients within a particular MELD/PELD score shall be based on total waiting time currently and previously accrued at that score on the same waiting list registration added to waiting time accrued at any higher MELD/PELD score. For example, if there are 2 persons with a MELD score of 30 who were both of identical blood type with the donor, the patient with the longest accrued waiting time in MELD score 30 or higher would receive the first offer. Waiting time will not be accrued by patients awaiting a liver transplant while they are registered on the UNOS Patient Waiting List as inactive.

Patients in Status 1 will receive waiting time points based on their waiting time in Status

1. Ten points will be accrued by the patient waiting for the longest period for a liver transplant and proportionately fewer points will be accrued by those patients with shorter tenure. For example, if there were 75 persons of O blood type waiting who were of a size compatible with a blood group O donor, the person waiting the longest would accrue 10 points (75/75 x 10). A person whose rank order was 60 would accrue 2 points. ((75-60)/75 x 10 = 2).

3.6.4 **Degree of Medical Urgency**. Each patient is assigned a status code or mortality risk score (probability of candidate death) which corresponds to how medically urgent it is that the patient receive a transplant.

3.6.4.1 **Adult Patient Status**. Medical urgency is assigned to an adult liver transplant patient (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1, or the patient's mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A patient who does not meet the criteria for Status 1, or have a MELD score that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency, may nevertheless be assigned to Status 1 or a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1 criteria or the MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the Status 1 and MELD criteria. During the initial implementation of the MELD/PELD scoring system, the minimum listing criteria in effect prior to implementation of the MELD/PELD system (a CTP score of 7) shall remain in effect,

Status	Definition
7	A patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	A patient greater than or equal to 18 years of age listed as Status 1 has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as:

(i) fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin>15mg%), marked prolongation of the INR (i.e., >2.5), or hypoglycemia.; or

(ii) primary non-function of a transplanted liver within 7 days of implantation; or

(i) hepatic artery thrombosis in a transplanted liver within 7 days of implantation; or

(iii) acute decompensated Wilson's disease.

Patients who are listed as a Status 1 automatically revert back to their most recent MELD Score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with MELD laboratory values in accordance with Policy 3.6.4.1.1 (Adult Patient Recertification and Reassessment Schedule) at the time listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. In those Regions that have agreed to allow UNOS RRB staff to review standard Status 1 cases, the RRB will only review Status 1 exceptional cases. A completed Liver Status 1 Justification Form must be received by UNOS on UNet^{sm} for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNET^{sm} when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent MELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other adult liver transplant candidates on the UNOS Patient Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNOS computer system for the prognostic factors specified in Table 1. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 1
Model for End-Stage Liver Disease (MELD) Scoring System

Prognostic Factor	Regression Coefficient	Std. Error	*P*
Serum creatinine (Log_e value)	**0.957**	**0.142**	**<0.01**
Serum bilirubin (Log_e value)	**0.378**	**0.117**	**<0.01**
INR (Log_e value)	**1.120**	**0.331**	**<0.01**

* The maximum serum creatinine considered within the MELD score equation will be 4.0mg/dl (i.e., for patients with a serum creatinine of greater than 4.0 mg/dl, the serum creatinine level will be set to 4.0 mg/dl). For patients on dialysis, defined as having 2 or more dialysis treatments within the prior week, the serum creatinine level will automatically be set

to 4.0 mg/dl.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a MELD score for each patient based on the following calculation:

MELD Score = 0.957 x Log_e(creatinine mg/dL) + 0. 378 x Log_e(bilirubin mg/dL) + 1.120 x Log_e (INR) + 0.643

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the MELD score calculation.

As an example, for a hypothetical patient with cirrhosis caused by hepatitis C virus who has a serum creatinine concentration of 1.9 mg/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:
MELD Score= (0.957 x Log_e1.9) + (0.378 x Log_e4.2) + (1.120 x Log_e1.2) + 0.643= 2.039

The MELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 20. The MELD score will be limited to a total of 40 points maximum.

3.6.4.1.1 **Adult Patient Reassessment and Recertification Schedule**. The appropriateness of the MELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Adult Patient Reassessment and Recertification Schedule

Status 1	Status recertification every 7 days.	**Laboratory values must be no older than 48 hours.**
MELD Score 25 or greater	Status recertification every 7 days.	**Laboratory values must be no older than 48 hours.**
Score <= 24but > 18	Status recertification every 1 month.	**Laboratory values must be no older than 7 days.**
Score <= 18 but >=11	Status recertification every 3 months.	**Laboratory values must be no older than 14 days.**
Score <= 10 but > 0	Status recertification every 12 months.	**Laboratory values must be no older than 30 days.**

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis), including the dates of the laboratory tests. In order to re-certify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a MELD score voluntarily, all laboratory values must be obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower MELD score. The patient may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the patient remains uncertified past the recertification due date for the previous lower score, the patient will be assigned a MELD score of 6. If a patient has no previous lower MELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a MELD score of 6.

NOTE: The amendment to Policy 3.6.4.1.1 (Adult Patient Reassessment and Recertification Schedule) shall be implemented following programming on the UNOS System.

3.6.4.2 **Pediatric Patient Status.** Medical urgency is assigned to a pediatric liver transplant patient (less than 18 years of age) based on either the criteria defined below for Status 1, or the patient's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance

with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A patient who does not meet the criteria for Status 1, does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgement of the patient's transplant physician, appropriately reflects the patient's medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to Status 1 or a higher PELD (less than 12 years of age) or MELD (12-17 years old) score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1 criteria or the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the Status 1 and PELD or MELD criteria. ~~Data required to compute the MELD score (creatinine, INR, bilirubin) must be entered for all candidates 12 years and older.~~

Status	Definition
7	A pediatric patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	A pediatric patient listed as Status 1 is located in the hospital's Intensive Care Unit (ICU) due to acute or chronic liver failure, has a life expectancy without a liver transplant of less than 7 days and meets at least 1 of the following criteria:

(i) Fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin>15mg%), marked prolongation of the INR (i.e., >2.5), or hypoglycemia.

(ii) Primary non-function of a transplanted liver within 7 days of implantation.

(iii) Hepatic artery thrombosis in a transplanted liver within 7 days of implantation.

(iv) Acute decompensated Wilson's disease.

(v) On mechanical ventilator.

(vi) Upper gastro-intestinal bleeding requiring at least 10 cc/kg of red blood cell replacement which continues or recurs despite treatment.

(vii) Hepatorenal syndrome: The presence of progressive deterioration of renal

function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine 3 times baseline. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 10 ml/kg/d; b) urine sodium < 10 mEq/l; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).

(viii) Stage III or IV encephalopathy unresponsive to medical therapy.

(ix) Refractory Ascites/Hepato-Hydrothorax: Severe persistent ascites or hepatohydrothorax, defined as any one of the following: unresponsive to diuretic and salt restriction therapy leading to respiratory distress, or requiring supplemental tube feeding, or requiring parenteral nutrition, or requiring supplemental oxygen, or requiring paracentesis.

(x) Biliary sepsis requiring pressor support of 5 mcg/kg/min of dopamine or greater.

With the exception of hospitalized pediatric liver transplant candidates with Ornithinine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I, patients who are listed as a Status 1 automatically revert back to their most recent PELD or MELD score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Patient Recertification and Reassessment Schedule) at the time of listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. A completed Liver Status 1 Justification Form must be received by UNOS on UNet^{sm} for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNet^{sm} when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other pediatric liver transplant candidates on the UNOS Patient Waiting List shall be assigned a mortality risk score calculated in accordance with the PELD (0-11 years) or MELD (12-17 years) scoring system.. For each liver candidate registration, the listing transplant center shall enter data on the UNOS computer system for the prognostic factors specified in Table 2 for pediatric candidates <12 years or Table 1 for pediatric candidates 12-17 years. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 2
Pediatric End-Stage Liver Disease (PELD) Scoring System

Prognostic Factor	Regression Coefficient	*P Value*
Albumin (Log_e value)	**-0.687**	**0.0111**
Total Bilirubin (Log_e value)	**0.480**	**0.0004**
INR (Log_e value)	**1.857**	**<0.0001**
Growth Failure (<- 2SD)	**0.667**	**0.009**
Age (<1 Yr.)*	**0.436**	**0.11**

* Scores for patients listed for liver transplantation before the patient's first birthday continue to include the value assigned for age (<1 Year) until the patient reaches the age of 24 months.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a PELD score for each patient based on the following calculation:

PELD Score= 0.436 (Age (<1 YR.)) – 0.687 x Log_e(albumin g/dL) + 0. 480 x Log_e(total bilirubin mg/dL) + 1.857 x Log_e (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the PELD score calculation. Growth failure will be calculated based on age and gender using the current CDC growth chart.

As an example, for a hypothetical patient 6 months of age with growth failure (<- 2 standard deviations) who has a serum albumin concentration of 1.9 g/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

PELD Score = 0.436 – (0.687 x Log_e1.9) + (0.480 x Log_e 4.2) + (1.857 x Log_e 1.2) + 0.667 = 1.689

The PELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 17.

3.6.4.2.1 **Pediatric Patient Reassessment and Recertification Schedule**. The appropriateness of the PELD or MELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Pediatric Patient Reassessment and Recertification Schedule

Status 1	**Status recertification every 7 days.**	**Laboratory values must be no older than 48 hours.**
PELD/MELD Score 25 or greater	**Status recertification every 14 days.**	**Laboratory values must be no older than 72 hours.**
Score < =24 but > 18	**Status recertification every 1 month.**	**Laboratory values must be no older than 7 days.**
Score <= 18 but >=11	**Status recertification every 3 months.**	**Laboratory values must be no older than 14 days.**
Score <= 10	**Status recertification every 12 months.**	**Laboratory values must be no older than 30 days.**

This reassessment and recertification must be based on the most recent

clinical information (e.g., laboratory test results and diagnosis) including the dates of the laboratory tests. In order to recertify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a PELD/MELD score voluntarily, all laboratory values must be obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's PELD/MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower PELD/MELD score. The patient may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the patient remains uncertified past the recertification due date for the previous lower score, the patient will be assigned a PELD score of 6. If a patient has no previous lower PELD/MELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a PELD/MELD score of 6 or will remain at the uncertified PELD score if it is less than 6.

NOTE: The amendments to Policy 3.6.4.2 (Pediatric Patient Status) and Policy (3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) shall be implemented following programming on the UNOS System.

3.6.4.3 Pediatric Liver Transplant Candidates with Metabolic Diseases (e.g., OTC or Crigler-Najjar Disease Type I). A pediatric liver transplant candidate with a metabolic disease such as Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I shall be assigned the medical urgency ranking, either Status 1 or the PELD (less than 12 years old) or MELD (12-17 years old) score, that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. The patient, if not already a Status 1, may be upgraded to a Status 1 if the patient is hospitalized for an acute exacerbation of their disease. The patient shall remain a Status 1 as long as he or she remains hospitalized. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD or MELD score is requested must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher PELD or MELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

NOTE: The amendment to Policy 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases). shall be implemented pending programming on the UNOS System.

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). Patients with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the waiting list as specified below. A patient with an HCC tumor that is greater than or equal to 2 cm and less than 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months.

(i) The patient has undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread and/or macrovascular involvement (i.e., portal or hepatic veins). A pre-listing biopsy is not mandatory but the lesion must meet the following imaging criteria. The assessment of the patient should include ultrasound of the patient's liver, a computerized tomography (CT) or magnetic resonance

imaging (MRI) scan of the abdomen that documents the tumors and a CT of the chest that rules out metastatic disease. In addition, the patient must have at least one of the following: a vascular blush corresponding to the area of suspicion seen on the above imaging studies, an alpha-fetoprotein level of >200 ng/ml, an arteriogram confirming a tumor, a biopsy confirming HCC, chemoembolization of lesion, radio frequency, cryo, or chemical ablation of the lesion. The alpha-fetoprotein level is required for all HCC exception applications. Patients with chronic liver disease who have a rising alpha-fetoprotein level ≥500 nanograms may be listed with a MELD/PELD score equivalent to an 8% mortality risk without RRB review even though there is no evidence of a tumor based on imaging studies.

(ii) The patient is not a resection candidate.

Patients will receive additional MELD/PELD points equivalent to a 10% increase in candidate mortality to be assigned every 3 months until these patients receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the patient to receive the additional 10% mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the patient's HCC priority scores. Patients meeting criteria based on an alpha-fetoprotein level of ≥ 500 nanograms, as specified in (i), must continue to demonstrate an ongoing rise in the alpha-fetoprotein level in order to extend the application.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. For patients whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

A patient not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the patient must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. Patients meeting all of the criteria in (i) and (ii) will receive a MELD/PELD score based on the tumor stage as described above without RRB review. All other patients with HCC including those with downsized tumors (i.e. having undergone ablative therapy) whose original/presenting tumor was greater than a Stage T2), must be referred to the applicable RRB for prospective review.

If the initial request is denied by the RRB, the center may appeal but the patient will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

For those patients who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the UNOS Policy Compliance Department If the pathology report does not show

evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.

Table 3
American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification (1)

Classification	Definition
TX, NX, MX	Not assessed
TO, NO, MO	Not found
T1	1 nodule <=1.9 cm
T2	One nodule 2.0-5.0 cm; two or three nodules, all <3.0 cm
T3	One nodule >5.0 cm; two or three nodules, at least one >3.0 cm
T4a	Four or more nodules, any size
T4b	T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound
N1	Regional (portal hepatis) nodes, involved
	M1 Metastatic disease, including extrahepatic portal or hepatic vein involvement
Stage 1	T1
Stage II	T2
Stage III	T3
Stage IVA1	T4a
Stage IVA2	T4b
Stage IVB	Any N1, any M1

Reference

1. American Liver Tumor Study Group – A Randomized Prospective Multi-Institutional Trial of Orthotopic Liver Transplantation or Partial Hepatic Resection with or without Adjuvant Chemotherapy for Hepatocellular Carcinoma. Investigators Booklet and Protocol. 1998.

3.6.4.4.1 **Pediatric Liver Transplant Candidates with Hepatoblastoma.** A pediatric patient with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be assigned the medical urgency ranking, either Status 1 or the PELD (less than 12 years old) or MELD (12-17 years old) score, that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD (less than 12 years old) or MELD (12-17) years old) score is requested must receive prospective approval by the applicable RRB, within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher PELD (less than 12 years old) or MELD (12-17) score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

NOTE: The amendment to Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma). shall be implemented pending programming on the UNOS System.

3.6.4.5 Liver Candidates with Exceptional Cases. Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees. Exceptions to MELD/PELD score must be reapplied every three months; otherwise the patient's score will revert back to the patient's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the patient will be assigned a MELD/PELD score based on current laboratory values. Centers may apply for a MELD/PELD score equivalent to a 10% increase in candidate mortality every 3 months as long as the patient meets the original criteria. Extensions shall undergo prospective review by the RRB. **A patient's approved score will be maintained if the center enters the extension application more than 3 days prior to the due date and the RRB does not act prior to that date (i.e., the patient will not be downgraded if the RRB does not act in a timely manner). If the extension application is subsequently denied then the patient will be assigned the laboratory MELD score.**

NOTE: The amendment to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) shall be implemented following programming on the UNOS system. (Bolded language is from November 03 updates)

3.6.4.5.1 Liver Candidates with Hepatopulmonary Syndrome (HPS). Patients with a clinical evidence of portal hypertension, evidence of a shunt, and a $PaO_2 < 60$ on room air may be referred to the RRB for consideration of a MELD score that would provide them a reasonable probability of being transplanted within 3 months. Patients should have no significant clinical evidence of underlying primary pulmonary disease.

3.6.4.5.2 Liver Candidates with Familial Amyloidosis or Primary Oxaluria. Patients with familial amyloidosis or primary oxaluria may be referred to the RRB for consideration of a MELD score that would allow them to be transplanted within 3 months.

3.6.4.6 On-Site Review of Status 1 Patient Listings. If a transplant center's listing of patients as Status 1 has been disapproved on 3 occasions at the final review of the applicable regional review board, and the patients receive a transplant while listed at the disapproved status, then UNOS shall conduct an on-site review of that center's Status 1 patient listings. The listing center shall reimburse all necessary and reasonable expenses incurred by UNOS in performing this on-site review. If there are no policy violations and the disapproved listings are found to be appropriate, the center will not be responsible for the necessary and reasonable expenses incurred by UNOS while performing the on-site review.

3.6.4.7 Combined Liver-Intestine Candidates. Patients awaiting a combined liver-intestine transplant who are registered on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. The center must verify that an intestinal transplant is required and took place.

NOTE: New Policy 3.6.4.7 (Combined Liver-Intestine Candidates) shall be granted final approval and implemented

following programming on the UNOS system.

3.6.5 **Center Contact and Acceptance**. Livers shall be offered in descending computer print-out order but the offering calls may be made concurrently (e.g., 5 liver teams may be called and given donor information provided that each team is told its priority number for the liver offer). Policy 3.4.1 (Time Limit for Acceptance) assures that each team will know within one hour whether or not another center with a patient who has higher points has accepted or rejected the offer.

3.6.5.1 **Execution of the UNOS Liver Match System.** The UNOS match system for liver allocation shall be executed within 8 hours prior to the initial liver offer. This match system printout of the liver transplant patient waiting list shall be utilized by the Host OPO for placement of the donor liver. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in specific medical information related to the liver donor. Any re-execution of the liver match system for the same donor for other reasons must be retrospectively reviewed by the Regional Review Board. This policy shall not apply to a donor liver that has been recovered and has not been placed within 2 hours of organ recovery.

3.6.6 **Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased.** If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a deceased 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 liver waiting lists and shall notify UNOS within 24 hours of the event. If the deceased donor liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a living donor, the listing center, or centers if the patient is multiple listed, shall immediately transfer that patient to inactive status until the patient requires a subsequent transplant or one year following the date of the patient's prior transplant, whichever is the first to occur. If the patient has not returned to active status during this one-year period, then the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the living donor recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. Data necessary to calculate the patient's current MELD or PELD score is required upon removal from the waiting list.

3.6.7 **UNOS Organ Center Assistance with Liver Allocation**. It is recommended that the UNOS Organ Center be notified when a liver donor is identified and provided all clinical information that is necessary to offer the liver to potential recipients on the UNOS Patient Waiting List. Upon request by the OPO, the Organ Center shall attempt to locate a liver recipient on the UNOS Patient Waiting List or identify backup recipients for the liver.

3.6.8 **Local Conflicts**. Regarding allocation of livers, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the UNOS Liver and Intestinal Organ Transplantation Committee and Board of Directors.

3.6.9 **Minimum Information for Liver Offers.**

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to OPTN Policy 3.4.1 (Time Limit for Acceptance); however, this

requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

(i) Donor name and OPTN Donor I.D. number, age, sex, race, height and weight;
(ii) ABO type;
(iii) Cause of brain death/diagnosis;
(iv) History of treatment in hospital including current medications, vasopressors and hydration;
(v) Current history of hypotensive episodes, urine output and oliguria;
(vi) Indications of sepsis;
(vii) Social and drug activity histories;
(viii) Vital signs including blood pressure, heart rate and temperature;
(ix) Other laboratory tests within the past 12 hours including:
  (1) Total Bilirubin
  (2) ALT
  (3) INR (PT if INR not available)
  (4) Alkaline phosphatase
  (5) GGT
  (6) WBC
  (7) HH
  (8) Creatinine;
(x) Arterial blood gas results;
(xi) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred).

3.6.9.2 **Listing Accuracy and Appropriateness.** Any instance in which an organ is allocated to a recipient center for a transplant candidate and the Host OPO or any UNOS Member questions the accuracy or appropriateness of the candidate's status may be reported retrospectively to the Host OPO's Regional Review Board with reasons for the concern. Upon receipt of two such reports regarding cases from the same institution within a one-year period, the Review Board shall refer the matter to the UNOS Membership and Professional Standards Committee with a request for an on-site audit of the institution.

3.6.10 **Allocation of Livers for Other Methods of Hepatic Support.** A liver shall not be utilized for other methods of hepatic support prior to being offered first for transplantation. Prior to being utilized for other methods of hepatic support, the liver shall be offered by the UNOS Organ Center in descending point order to all Status 1 candidates, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) in the Host OPO's region followed by Status 1 candidates, and then by all candidates in order of the MELD PELD scores (probability of candidate death) in all other regions. If the liver is not accepted for transplantation within 6 hours of attempted placement by the Organ Center, the Organ Center shall offer the liver to Status 1, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) for whom the liver will be considered for other methods of hepatic support. Livers allocated for other methods of hepatic support shall be offered first locally, then regionally, and then nationally in descending point order to transplant candidates designated for other methods of hepatic support.

3.6.11 **Allocation of Livers for Segmental Transplantation.** A transplant center that accepts a liver for segmental transplantation shall offer the remaining segment:

(i) in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the

donor organ procurement procedure has started, or

(ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

3.6.12 **Transition of Currently Listed Patients.** Patients listed as Status 2A at the time the MELD system is implemented will be grandfathered into the new system for a period of 30 days following the implementation date. Patients who are still listed as Status 2A at the end of 30 days would be converted to a MELD score based on the MELD criteria. These patients shall be listed on the UNOS match-run printout ahead of patients who are listed by MELD scores and stratified based on the liver allocation criteria specified in UNOS Policy 3.6 in effect prior to implementation of the MELD and PELD scoring systems. At the end of the 30 days, patients still in Status 2A will receive 30 days of waiting time towards their current MELD score. Those patients who no longer meet the Status 2A criteria during the first 30 days will receive time accrued in Status 2A since the implementation.

Patients listed as Status 2B or 3 at the time the MELD and PELD systems are implemented will be converted to a MELD or PELD score based on the MELD or PELD criteria. All waiting time accrued by these patients under the prior status system would apply toward their eligibility for a liver offer under the MELD and PELD system for a period of 1 year while the patients are listed at their initial or lower mortality risk scores under the new system criteria. After 1 year, this previously accrued waiting time will not be counted and only the waiting time accrued under the MELD/PELD system from the date of its implementation would apply toward liver allocation thereafter. If the data required to calculate the MELD or PELD score (as applicable) have not been entered into the UNet^{sm} system at the time of implementation, the patient will automatically be assigned a MELD or PELD score of 6.

3.6.12.1 **Transition for Currently Listed Status 2B HCC Patients.** Patients listed as Status 2B under the previous HCC criteria at the time the MELD and PELD systems are implemented will receive a MELD score equivalent to a 15% probability of candidate death within 3 months. No additional testing will be required for these patients unless a center wishes to apply for the T2 MELD score as described in policy 3.6.4.4. In these cases, the center must submit documentation that the patient meets the criteria specified in 3.6.4.4(i). Previously accrued waiting time will be applied to the patient's initial or lower MELD score, for a period of one year. These patient's must be reevaluated at 3-months, at which time the new criteria will be applied.

3.7 **ALLOCATION OF THORACIC ORGANS.** This policy describes how thoracic organs (hearts, heart-lung combinations, single and double lungs) are to be allocated to patients awaiting a thoracic organ transplant.

3.7.1 **Exceptions.** Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), and 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

3.7.1.1 Exception for Sensitized Patients. The transplant surgeon or physician for a patient awaiting thoracic organ transplantation may determine that the patient is "sensitized" such that the patient's antibodies would react adversely to certain donor cell antigens. It is permissible not to use the allocation policies set forth in Policy 3.7 for allocation of a particular thoracic organ when all thoracic organ transplant centers within an OPO and the OPO agree to allocate the thoracic organ to a sensitized patient because results of a crossmatch between the blood serum of that patient and cells of the thoracic organ donor are negative (i.e., the

patient and thoracic organ donor are compatible). The level of sensitization at which a patient may qualify for this exception is left to the discretion of the listing transplant center, and subject to agreement among all thoracic organ transplant centers within an OPO and the OPO. Sensitization is not a qualifying criterion for assigning a patient to a heart status category as described in UNOS Policies 3.7.3 (Adult Patient Status) and 3.7.4 (Pediatric Patient Status).

3.7.2 **Geographic Sequence of Thoracic Organ Allocation.** Thoracic organs are to be allocated locally first, then within the following zones in the sequence described in Policy 3.7.10 and Policy 3.7.11. Four zones will be delineated by concentric circles of 500, 1,000, and 1,500 nautical mile radii with the donor hospital at the center. Zone A will extend to all transplant centers which are within 500 miles from the donor hospital but which are not in the local area of the donor hospital. Zone B will extend to all transplant centers that are at least 500 miles from the donor hospital but not more than 1,000 miles from the donor hospital. Zone C will extend to all transplant centers that are located beyond 1,000 miles from the donor hospital. Zone D will extend to all transplant centers that are located beyond 1,500 miles from the donor hospital.

3.7.3 **Adult Patient Status.** Each patient awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the patient receive a transplant. Medical urgency is assigned to a heart transplant patient who is greater than or equal to 18 years of age at the time of listing as follows:

Status	Definition

1A A patient listed as Status 1A is admitted to the listing transplant center hospital and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

(i) left and/or right ventricular assist device implanted Patients listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
(ii) total artificial heart;
(iii) intra-aortic balloon pump; or
(iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(b) Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias (Patient sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by UNOS Policy 3.7.1.1 (Exception for Sensitized Patients). Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending

physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(d) Continuous infusion of a single high-dose intravenous inotrope (e.g., dobutamine >/= 7.5 mcg/kg/min, or milrinone >/= .50 mcg/kg/min), or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures; Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same patient.

(e) ~~A patient who does not meet the criteria specified in (a), (b), (c) or (d) may be listed as Status 1A if the patient is admitted to the listing transplant center hospital and has a life expectancy without a heart transplant of less than 7 days. Qualification for Status 1A under this criterion is valid for 7 days and may be recertified by an attending physician for one additional 7 day period.~~

A patient who does not meet the criteria for Status 1A may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using acceptable medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. The justification must be prospectively reviewed and approved by the Regional Review Board before the patient can be listed as Status 1A. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria. A patient's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion requires ~~a conference with the applicable UNOS Regional Review Board~~ prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the patient's transplant physician may list the patient as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation ~~and Membership and Professional Standards~~ Committees.

For all adult patients listed as Status 1A, a completed Heart Status 1A Justification Form must be received by UNOS on UNet^{sm} in order to list a patient As Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.3. Patients listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet^{sm} by an attending physician within the time frames described in the definitions of status 1A(a)-(~~c~~d) above.

1B A patient listed as Status 1B has at least one of the following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or
(bb) continuous infusion of intravenous inotropes.

For all adult patients listed as Status 1B, a completed Heart Status 1B Justification Form must be received by UNOS on UNet^{sm} in order to list a patient within one working day of a patient's listing as Status 1B. A patient who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this

status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria.

2 A patient who does not meet the criteria for Status 1A or 1B is listed as Status 2.

7 A patient listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any patients upon expiration of any limited term for any listing category, UNOS shall notify a responsible member of the relevant transplant team.

NOTE: Amendments to Policy 3.7.3 1A(e) (Adult Patient Status) shall be implemented pending programming on the UNOS system.

1B A patient listed as Status 1B has at least one of the following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or
(bb) continuous infusion of intravenous inotropes.

For all adult patients listed as Status 1B, a completed Heart Status 1B Justification Form must be received by UNOS on UNet[sm] in order to list a patient within one working day of a patient's listing as Status 1B. A patient who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria.

2 A patient who does not meet the criteria for Status 1A or 1B is listed as Status 2.

7 A patient listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any patients upon expiration of any limited term for any listing category, UNOS shall notify a responsible member of the relevant transplant team.

3.7.4 <u>Pediatric Patient Status</u>. Each patient awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the patient receive a transplant. Medical urgency is assigned to a heart transplant patient who is less than 18 years of age at the time of listing as follows: Pediatric heart transplant patients who remain on the waiting list at the time of their 18th birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in Policy 3.7.4.

Status Definition

1A A patient listed as Status 1A meets at least one of the following criteria:

(a) Requires assistance with a ventilator;

(b) Requires assistance with a mechanical assist device (e.g., ECMO);

(c) Requires assistance with a balloon pump;

(d) A patient less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a patient may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

(e) Requires infusion of high dose (*e.g.*, dobutamine > 7.5 mcg/kg/min or milrinone > .50 mcg/kg/min) or multiple inotropes (*e.g.*, addition of dopamine at > 5 mcg/kg/min); or

(f) A patient who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the patient has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable UNOS Regional Review Board.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

For all pediatric patients listed as Status 1A, a completed Heart Status 1A Justification Form must be received by UNOS on UNet^{sm} in order to list a patient As Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Patients who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these patients are re-listed on UNet^{sm} as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above

1B A patient listed as Status 1B meets at least one of the following criteria:

(a) Requires infusion of low dose single inotropes (*e.g.*, dobutamine or dopamine < 7.5 mcg/kg/min);

(b) Less than six months old and does not meet the criteria for Status 1A; or

(c) Growth failure *i.e.,* + 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the patient's growth at two different times, second, calculating the patient's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.,* (patient's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

For all pediatric patients listed as Status 1B, a completed Heart Status 1B Justification Form must be received by UNOS on UNet[sm] in order to list a patient as Status 1B. A patient who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria.

2 A patient who does not meet the criteria for Status 1A or 1B is listed as Status 2.

7 A patient listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any patients upon expiration of any limited term for any listing category, UNOS shall notify a responsible member of the relevant transplant team.

3.7.5 **Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates.** Within each heart status, a heart retrieved from an adolescent organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, an adolescent organ donor is defined as an individual who is 11 years of age or older, but less than 18 years of age.

3.7.6 **~~Status of Patients Awaiting~~ Lung Allocation ~~Transplantation~~**. ~~All patients awaiting isolated lung transplantation are considered to be the same urgency status for the purposes of thoracic organ allocation.~~ Candidates are assigned priority in lung allocation as follows:

3.7.6.1 Candidates Age 12 and Older. Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The OPTN/UNOS Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.

Table 1

Factors Used to Predict
Risk of Death on the Lung Transplant Waitlist

1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic (Group A, C, D[1]
3. O_2 required at rest (A, C, D)
4. Age
5. Body mass index (BMI)
6. Insulin dependent diabetes
7. Functional status (New York Heart Association (NYHA) class)
8. Six-minute walk distance
9. Ventilator use
10. Diagnosis

[1]Group A includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.
Group B includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases.
Group C includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.
Group D includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant).

Table 2

Factors That Predict
Survival After Lung Transplant

1. FVC (Group B, D[9])
2. PCW pressure ≥ 20 (Group D[9])
3. Ventilator use
4. Age
5. Creatinine
6. Functional Status (NYHA class)
7. Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple patients.

As an example, assume that a donor lung is available, and both Patient X and Patient Y are on the waiting list. Taking into account all diagnostic and prognostic factors, Patient X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Patient X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Patient Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize patients based on the difference between each patient's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

	Patient X	Patient Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
e. **Lung Allocation Score**	**74.3**	**78.0**

In the example here, Patient X's raw allocation score would be 84.1 and Patient Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by patients and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Patient X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Patient Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Patient Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Patient X that results in the lowest contribution to the Lung Allocation Score for that variable field will be selected for the candidate. Programs are permitted to override the system and enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Use of the override feature results in an automatic review by the Thoracic Organ Transplantation Committee to determine whether the override values selected are appropriate and whether further action is warranted.

3.7.6.2 Candidates Age 0 - 11. Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time.

3.7.6.3 Candidate Variables in UNet[sm]. Entry into UNet[sm] of candidate clinical data responding to the variables shown in Tables 1 and 2 above, as they may be amended from time to time, is required when listing a candidate for lung transplantation. Candidates with no clinical data upon listing are assigned a Lung Allocation Score of zero, the score with the lowest priority. Candidates with incomplete clinical data upon listing are assigned a default value for each incomplete variable field. The value

3.7.6.3.1 Candidate Variables in UNet[sm] upon Implementation of Lung Allocation Scores Described in Policy 3.7.6. Candidates registered on the lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive a Lung Allocation Score of zero, the score with the lowest priority.

3.7.6.3.2 Updating Candidate Variables. Programs may update their candidates' clinical data at any time they believe a change in patient medical condition warrants such modification. Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. The frequency of updating those candidate variables that are obtainable only by heart catheterization will be left to the discretion of the transplant center.

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3.7.6.4 Lung Candidates With Exceptional Cases. Special cases require review by the Lung Regional Review Board. The transplant center will accompany each request for special case review with a supporting narrative. The Thoracic Committee shall establish guidelines for special case review by the Lung RRB's.

3.7.7 **Allocation of Thoracic Organs to Heart-Lung Candidates.** Candidates for a heart-lung transplant shall be registered on the individual UNOS Patient Waiting list for each organ. When the patient is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the patient is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart.

3.7.8 **ABO Typing for Heart Allocation.** Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

(i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;

(ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;

(iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;

(iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.

(v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.

Following allocation for all born transplant candidates who have blood types that are compatible with donors hearts will be allocated locally first and then within zones in the sequence described in Policy 3.7.10, by heart status category to pediatric heart candidates less than one year of age who have a blood type that is incompatible with the donor's blood type if the candidate is listed with the blood type "Z" designation. Following allocation for incompatible pediatric heart candidates less than one year of age, hearts will be allocated, locally first and then within zones in the sequence described in Policy 3.7.10, to patients listed *in utero.*

3.7.8.1 Heart Allocation to Pediatric Candidates Registered Under Blood Type "Z". For pediatric candidates who will accept a heart from a donor of any blood type, the blood type "Z" designation may be added as a suffix to the actual blood type (e.g., "AZ") of a pediatric patient less than one year of age, or used alone if actual blood type is not known for *in utero* candidates.

3.7.8.2 ABO Typing for Lung Allocation. Patients who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before patients who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant

3.7.9 **Time Waiting for Thoracic Organ Candidates.** Calculation of the time a patient has been waiting for a thoracic organ transplant begins with the date and time the patient is first registered as active on the UNOS Patient Waiting List. Waiting time will not be accrued by patients awaiting a thoracic organ transplant while they are registered on the UNOS Patient Waiting List as inactive. When time waiting is used for thoracic organ allocation, a patient will receive a preference over other patients who have accumulated less waiting time within the same status category. Where applicable, ~~W~~waiting time accrued by a patient for a single thoracic organ transplant (heart or single lung) while waiting on the UNOS Patient Waiting List also may be accrued for a second thoracic organ, when it is determined that the patient requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a patient for a multiple thoracic organ transplant while

waiting on the UNOS Patient Waiting List may be transferred to the waiting list for a single thoracic organ transplant.

3.7.9.1 Waiting Time Accrual for Heart Candidates. Patients listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the patient is upgraded to a higher status. For example, a patient who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the patient is downgraded to a Status 2 for another 3 weeks, then the patient will have 4 months of total accrued time. If the patient subsequently is upgraded for another week as a Status 1A, then the patient's Status 1A waiting time will be 2 weeks.

3.7.9.2 Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6 ~~with Idiopathic Pulmonary Fibrosis (IPF)~~. Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero~~A lung transplant candidate diagnosed with IPF shall be assigned 90 days of additional waiting time upon the candidate's registration on the UNOS Patient Waiting List~~

3.7.10 **Sequence of Heart Allocation**. Donor hearts shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

Local

1. Status 1A patients
2. Status 1B patients
3. Status 2 patients

Zone A
4. Status 1A patients
5. Status 1B patients

Zone B
6. Status 1A patients
7. Status 1B patients

Zone A
8. Status 2 patients

Zone B
9. Status 2 patients

Zone C
10. Status 1A patients
11. Status 1B patients
12. Status 2 patients

Zone D

13 Status 1A patients
14. Status 1B patients
15. Status 2 patients

3.7.11 **Sequence of Adult Donor Lung Allocation ~~of Lungs~~.** ~~Patients~~ Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation ~~purposes~~. If

one lung is allocated to a ~~patient~~ candidate needing a single lung transplant, the other lung will be then allocated to another ~~patient~~ candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to ~~patients~~candidates in Zone A, then to ~~patients~~candidates in Zone B, then to ~~patients~~candidates in Zone C, and finally to ~~patients~~candidates in Zone D. In each of those five geographic areas, ~~patients~~candidates will be grouped so that ~~patients~~candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to ~~patients~~candidates in that ABO identical type. If the lungs are not allocated to ~~patients~~candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining ~~patients~~candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

i. First locally to ABO identical ~~patients~~candidates age 12 and older according to Lung Allocation Score in descending order;
ii. Next, locally to ABO compatible ~~patients~~candidates age 12 and older according to Lung Allocation Score in descending order;
iii. Next, locally to ABO identical candidates 0 – 11 years old according to length of waiting time;
iv. Next, locally to ABO compatible candidates 0 – 11 years old according to length of waiting time;
v. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
vi. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of waiting time;
viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of waiting time;
ix. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
x. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
xi. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of waiting time;
xii. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of waiting time;
xiii. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
xiv. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
xv. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of waiting time;
xvi. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of waiting time;
xvii. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
xviii. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
xix. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of waiting time; and
xx. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of waiting time.

3.7.11.1 Sequence of Pediatric Donor Lung Allocation. Candidates 0 – 11 years old

awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, and finally, to candidates in Zone D. In each of those five geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for lungs from donors 0 11 years old is as follows:

i. First locally to ABO identical candidates 0 – 11 years old according to length of time waiting;
ii. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;
iii. Next, locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
iv. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
v. Next, locally to ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
vi. Next, locally to ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;
viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;
ix. Next, to ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
x. Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
xi. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xii. Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xiii. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;
xiv. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;
xv. Next, to ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
xvi. Next, to ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
xvii. Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

xviii. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

xix. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of time waiting;

xx. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of time waiting;

xii. .Next, to ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

xxii. Next, to ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

xxiii. Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

xxiv. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

xxv. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of time waiting;

xxvi. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of time waiting;

xxvii. Next, to ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

xxviii. Next, to ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

xxix. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

xxx. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidate s age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, and finally, to candidates in Zone D. In each of those five geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the compatible (but not identical) with that of the donor. In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

i. First locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;

ii. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;

iii. Next, locally to ABO identical candidates 0 – 11 years old according to length of time waiting;

iv. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;

v. Next, locally to ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;

vi. Next, locally to ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;

vii. Next, to ABO identical candidates 12 – 17 years old in zone A according to Lung Allocation Score in descending order;

viii. Next, to ABO compatible candidates 12 – 17 years old in zone A according to Lung Allocation Score in descending order;

ix. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;

x. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;

xi. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

xii. Next, to ABO compatible candidates 18 years old and older in Zone A according to

Lung Allocation Score in descending order;

xiii. Next, to ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

xiv. Next, to ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

xv. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;

xvi. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;

xvii. Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

xviii. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

xix. Next, to ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

xx. Next, to ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

xxi. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of time waiting;

xxii. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of time waiting;

xxiii Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

xxiv. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

xxv. Next, to ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

xxvi. Next, to ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

xxvii. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of time waiting;

xxviii. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of time waiting;

xxix. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

xxx. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

NOTE: The amendments to Policy 3.7.6 (Lung Allocation, Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), and 3.7.11 (Sequence of Adult Donor Lung Allocation) shall be implemented following programming on the UNOS System.

3.7.12 Minimum Information for Thoracic Organ Offers.

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;
(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;
(v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
(vi) Accurate height, weight, age and sex;
(vii) ABO type;
(viii) Interpreted electrocardiogram and chest radiograph;
(ix) History of treatment in hospital including vasopressors and hydration;

(x) Arterial blood gas results and ventilator settings; and
(xi) Echocardiogram, if the donor hospital has the facilities.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

3.7.12.2 Desirable Information for Heart Offers. With each heart offer, the donor center is encouraged to provide the recipient center with the following information:

(i) Coronary angiography for male donors over the age of 40 and female donors over the age of 45;
(ii) CVP or Swan Ganz instrumentation ;
(iii) Cardiology consult; and
(iv) Cardiac enzymes including CPK isoenzymes.

With each heart offer, it is reasonable for the transplanting center to request a heart catheterization of the donor where the donor history reveals one or more of the following:

(a) The donor is a male over the age of 40 or a female over the age of 45;
(b) Segmental wall motion abnormality;
(c) Troponin elevation;
(d) History of chest pain;
(e) Abnormal EKG consistent with ischemia or myocardial infarction; or
(f) Two or more of the following:
    i. History of hypertension
    ii. History of significant smoking
    iii. Intra-cerebral bleed
    iv. Strong family history of coronary artery disease
    v. History of Hyperlipidemia
    vi. History of diabetes
    vii. History of cocaine or amphetamine use

3.7.12.3 Essential Information for Lung Offers. In addition to the essential information specified above for a thoracic organ offer, the Host OPO or donor center shall provide the following specific information with each lung offer:

(i) Arterial blood gases on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2 within 2 hours prior to the offer;
(ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation, and should be arranged by the Host OPO or donor center. If the Host OPO or donor center lacks the personnel and/or technical capabilities to comply, the bronchoscopy responsibility will be that of the recipient center. The inability of the Host OPO or donor center to perform a bronchoscopy must be documented. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.1;
(iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;
(iv) Sputum gram stain with a description of the sputum character; and
(v) Smoking history.

3.7.12.4 Desirable Information for Lung Offers. With each lung offer, the Host OPO or donor center is encouraged to provide the recipient center with the following information:

(i) Mycology smear; and
(ii) Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested.

3.7.13 Status 1 Listing Verification. A transplant center which has demonstrated noncompliance with the Status 1 criteria specified in UNOS Policy 3.7.3 (Primary Allocation Criteria) for heart candidate registration shall be audited on a random basis and any recurrence of noncompliance will result in a recommendation to the Membership and Professional Standards Committee and Executive Committee that further Status 1 heart candidate registrations from that center shall be subject to verification by UNOS of the candidates' medical status prior to their Status 1 placement on the UNOS waiting list for a period of one year.

3.7.14 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased. If a heart, lung, or heart-lung 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 thoracic organ waiting lists for that transplanted organ and shall notify UNOS within 24 hours of the event. If the thoracic organ recipient is again added to a thoracic organ waiting list, waiting time shall begin as of the date and time the patient is relisted.

3.7.15 Local Conflicts Involving Thoracic Organ Allocation. Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the UNOS Thoracic Organ Transplantation Committee and the UNOS Board of Directors.

3.7.16 Allocation of Domino Donor Hearts. A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a patient who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the patients of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to UNOS Policy 3.7, or an approved variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the HCFA-designated service area of the OPO where the domino heart is procured.

3.7.17 Crossmatching for Thoracic Organs. The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.

NOTE: New Policy 3.7.17 (Crossmatching for Thoracic Organs) shall be effective January 1, 2005.

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.~~3~~4or 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.~~3~~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 patient or pursuant to Policy 3.5.~~3~~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^2, 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/m^2 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.~~1~~2 and the kidney must be paid back as specified in Policy 3.5.~~7~~5.

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.~~1~~2 and the kidney must be paid back as specified in Policy 3.5.~~7~~5.

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.~~1~~2 and the kidney must be paid back as specified in Policy 3.5.~~4~~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 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/m^2 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/m^2, 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 x 1 = 1). A person with the 60th longest time of waiting would be assigned 0.2 points (75-60)/75 x 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 November2003 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 ≥ 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.

3.9 ALLOCATION SYSTEM FOR ORGANS NOT SPECIFICALLY ADDRESSED. The following point system will be used for allocation of organs not specifically addressed elsewhere in UNOS policies.

3.9.1 Medical Urgency. For organs not specifically addressed, points are assigned for medical urgency as follows:

Patient Status Code	Points	Definition
1	4	A patient listed as Status 1 is at home and functioning normally. A patient listed as Status 1 is considered to be a patient for whom the transplant surgery would be an elective procedure.
2	8	A patient listed as Status 2 is home bound, requiring continuous medical care which can be self administered. Short hospitalizations for intercurrent problems are not considered justification for a change in status.
3	12	A patient listed as Status 3 is home bound, requiring continuous medical care with the assistance of an attendant. Short hospitalizations for intercurrent problems are not considered justification for a change in status.
4	16	A patient listed as Status 4 is continuously hospitalized. A Status 4 patient's medical condition necessitates continuous hospitalization.
5	20	A patient listed as Status 5 requires continuous hospitalization as well as intravenous inotropic drug therapy.
6	24	A patient listed as Status 6 requires continuous hospitalization. A Status 6 patient also requires a Mechanical Assist Device(s) (e.g. ventilator, total artificial heart, intra-aortic balloon pump) for survival.

3.9.2 Distance Criteria. The following points are assigned for the distance between transplant center and the donor as well as for the distance between the recipient and the transplant center:

Distance from Center (miles)	Points Donor	Points Recipient
0-50	12	6
50-500	10	5
500-1000	8	4

1000-1500	6	3
1500-2000	4	2
2000-2500	2	1
> 2500	0	0

3.9.3 **Organ Allocation to Multiple Organ Transplant Candidates**. Candidates for a multiple organ transplant where one of the required organs is a heart, lung or liver shall be registered on the individual UNOS Patient Waiting list for each organ. When the patient is eligible to receive a heart, lung or liver pursuant to UNOS Policies 3.6 (ALLOCATION OF LIVERS) and 3.7 (ALLOCATION OF THORACIC ORGANS) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case the organ shall be paid back pursuant to UNOS Policy 3.5.4 (Payback Requirements). This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with UNOS Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For patients awaiting a combined liver-intestine transplant, the liver may be allocated using the intestine list unless there is a Status 1 Liver patient in the Region.

3.9.4 **Local Conflicts**. Regarding allocation of organs not specifically addressed elsewhere in UNOS policies, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the appropriate organ-specific UNOS committee(s) and Board of Directors.

3.10 **BACK-UP FOR INACTIVE TRANSPLANT PROGRAMS.** Each UNOS center should address the issue of providing services for transplant programs that are temporarily inoperative.

3.11 **INTESTINAL ORGAN ALLOCATION**. The following policies apply to intestinal organ allocation which may include the stomach, small and/or large intestine or any portion of the gastro-intestinal tract as determined by the medical needs of individual patients.

3.11.1 **Degree of Medical Urgency**. Each patient shall be assigned one of the following status codes which correspond to the medical condition of the patient.

Status 7 A patient listed as a Status 7 is temporarily inactive; however, the patient continues accruing waiting time up to a maximum of 30 days. Patients who are considered to be temporarily unsuitable transplant candidates are listed as Status 7.

Status 1 A patient listed as a Status 1 has liver function test abnormalities and/or no longer has vascular access through the subclavian, jugular or femoral veins for intravenous feeding, or has other medical indications that warrant intestinal organ transplantation on an urgent basis.

Status 2 All patients awaiting intestinal organ transplantation who do not meet the criteria for Status 1 will be classified as Status 2.

3.11.2 **Geographic Sequence for Intestinal Organ Allocation.** Intestinal organs shall be allocated first to transplant candidates who are size compatible and have a blood type that is identical to that of the organ donor. These patients will be followed by candidates who have a blood type that is compatible to that of the organ donor. Allocation shall be based on length of time waiting and in accordance with the following sequence:

- To local Status 1 patients first;
- Local Status 2 patients;

- Status 1 patients in the Host OPO's region;
- Status 2 patients in the Host OPO's region;
- Status 1 patients in all other regions; and
- Status 2 patients in all other regions.

3.11.3 **Justification Form**. A Status 1 Justification Form must be ~~received by the UNOS Organ Center within 24 hours of a~~ submitted in UNet^{SM} for the patient's original listing as a Status 1 and each renewal as a Status 1.

NOTE: The amendment to Policy 3.11.3 (Justification Form shall be implemented following programming on the UNOS System. (Implemented June 29, 2004)

3.11.4 **Combined Intestine-Liver Organ Candidates**. For patients awaiting a combined intestine-liver transplant, the liver may be allocated by the local OPO to a local or regional intestine recipient based upon priority for receipt of the intestine using the intestine Waiting List unless there is a Status 1 liver patient locally or regionally. If the liver is voluntarily shared with the intestine regionally, a liver of identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO.

3.11.4.1 **Waiting Time Accrual for Combined Liver-Intestinal Organ Candidates.** Waiting time accrued by a patient for an isolated intestinal organ transplant while waiting on the UNOS Patient Waiting List also may be accrued for a combined liver-intestinal organ transplant, when it is determined that the patient requires the multiple organs.

3.11.5 **Removal of Intestinal Transplant Candidates from Intestine Waiting Lists When Transplanted or Deceased**. If an intestinal organ transplant candidate has received a transplant, 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 intestinal organ waiting lists and shall notify UNOS within 24 hours of the event. Except as specified in UNOS Policy 3.11.5.1, if the intestinal organ recipient is reinstated to an intestinal organ waiting list, waiting time shall begin as of the date and time the patient is relisted.

3.11.5.1 Waiting Time Reinstatement for Intestinal Organ Transplant Recipients. In those instances when there is immediate and permanent non-function of a transplanted intestinal organ, the patient may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For the purpose of this policy, immediate and permanent non-function shall be defined as an intestinal organ graft failure resulting in removal of the organ within the first 7 days following transplantation. Waiting time will be reinstated upon receipt by the UNOS Organ Center of a completed Intestinal Organ 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.

3.11.6 **Waiting Time for Intestinal Organ Transplant Candidates in an Inactive Status.** Patients shall be allowed to accrue an aggregate of 30 days inactive status waiting time. A patient's waiting time accrued during each occurrence of inactivation shall be calculated on a cumulative basis so that once the 30 day aggregate limit is reached no additional waiting time shall accrue on further occurrences of inactivation.