

### 3.0 ORGAN DISTRIBUTION

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

#### 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.***