全米臓器配分ネットワーク（ＵＮＯＳ）における胸部臓器の配分規定
（2004年6月25日版）

3.0 ORGAN DISTRIBUTION

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

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)-(~~e~~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.

3.7.4 Pediatric 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 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 **Lung Allocation**

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3.7.7 **Allocation of Thoracic Organs to Heart-Lung Candidates.**

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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

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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.