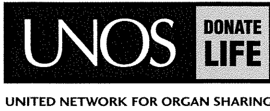

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Walter Graham, Executive Director

PUBLIC COMMENT NOTICE

To: OPTN/UNOS members and other interested persons

From: Douglas A. Heiney, Director
Department of Membership Services and Policy Development

Re: OPTN/UNOS policy proposal for public comment

Date: April 20, 2005

Attached for your consideration is a policy proposal regarding clarifications to the current lung allocation system that is being issued for public comment. This proposal addresses issues considered during recent meetings of the OPTN/UNOS Executive Committee, Thoracic Organ Transplantation Committee, Lung Allocation System Implementation Working Group and the Lung Allocation Subcommittee. The new lung allocation system is scheduled for implementation on May 4, 2005. As work has progressed on the programming and implementation of the new system several issues have arisen that necessitate further clarifications in OPTN/UNOS policy 3.7.6 and 3.7.9. The newly proposed policy clarifications are consistent with the original concepts described in the policies approved by the Board. The newly proposed clarifications provide additional detail regarding or specific application for some of the general constructs found in the original policy.

Following public comment and reconsideration by the appropriate committee(s), this proposal may be offered for consideration by the committee(s) to the OPTN/UNOS Board at its June 23-24, 2005 meeting. Please mail, fax, or email your comments on this proposal to UNOS by May 20, 2005.

UNOS appreciates receiving your response to these important issues.

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Background

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational organization. On October 1, 2000, UNOS received a federal contract to continue operation of the national Organ Procurement and Transplantation Network (OPTN) and development of an equitable, scientific and medically-sound organ allocation system. The OPTN is charged with developing by-laws and policies that maximize utilization of organs donated for transplantation, assuring the quality of care for transplant candidates and recipients, and addressing other complex medical issues related to organ transplantation in the United States. All by-laws and policies receive broad input from numerous constituencies including transplant candidates and recipients and family members, donors and donor families, the OPTN membership, and concerned individuals and organizations throughout the United States.

By-Laws and policies are adopted by the OPTN/UNOS Board of Directors pursuant to the UNOS contract with the United States Department of Health and Human Services (DHHS) and after circulation and discussion among organ transplant professionals and patient representatives. These by-laws and policies have been submitted to the Secretary of DHHS and are considered voluntary guidance to OPTN members unless recommended by the Board of Directors and approved by the Secretary of DHHS as OPTN rules and requirements enforceable under Section 1138 of the Social Security Act. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Instances of noncompliance with by-laws and policies may lead to disciplinary action, including, for example, designation as a member-not-in-good-standing by the Board of Directors. In addition, instances of non-compliance are reported to the Secretary of DHHS.

The proposal that follows addresses issues considered during recent meetings of the OPTN/UNOS Executive Committee, Thoracic Organ Transplantation Committee, Lung Allocation System Implementation Working Group and the Lung Allocation Subcommittee.

Following public comment and reconsideration by the appropriate committee(s), this proposal may be offered for consideration by the committee(s) to the OPTN/UNOS Board at its June 23-24, 2005 meeting in St. Louis, MO.

This policy proposal is also available for review on the OPTN and UNOS Internet Web sites at www.optn.org and www.unos.org. Comments on this proposal may be submitted electronically at these sites.

Circulation of Notice

UNOS maintains a public comment distribution list for policy and by-law proposals. To be included on the distribution list, submit a written request to UNOS at the address below. All policy and by-law proposals issued for public comment are mailed to the distribution list. UNOS typically accepts comments from the public for at least 45 days after publication of the proposals and public hearings on the proposals are arranged if warranted. The public comment period for this particular distribution is established at 30 days to accommodate the schedule for the Board of Directors meeting.

Comment Deadline

The proposal in this document is being issued for public comment on **April 20, 2005**. To be considered, comments must be submitted in writing, or by completing the enclosed Public Comment Response Form, and sent to the UNOS contact person at the following address by **May 20, 2005**:

United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218
FAX (804) 782-4896

UNOS Contact Persons

Inquiries regarding the policy proposal in this document should be made to the appropriate UNOS Regional Administrator at (804) 782-4800. The UNOS Regional Administrators are as follows:

Shannon Edwards (edwardsf@unos.org)
Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 4 - Oklahoma, Texas
Region 9 - New York, Western Vermont

Betsy Gans (gansel@unos.org)
Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

Clifton McClenney (mcclence@unos.org)
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Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

***Chrystal Oley-Graybill (graybioe@unos.org)**
*Region 5 - Arizona, California, Nevada, New Mexico, Utah
*Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
*Region 10 - Indiana, Michigan, Ohio

*** From April 11, 2005 through May 13, 2005, Please use the following contact information:**

Region 5- Betsy Gans
Region 7 - Shannon Edwards
Region 10 - Cliff McClenney

Allocation of Lungs: Proposed Modifications to OPTN/UNOS Policy 3.7.6 (Lung Allocation) and Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates)

1. Summary/Performance Objective-Aim

On June 25, 2004, the OPTN/UNOS Board of Directors unanimously passed a resolution from the OPTN/UNOS Thoracic Organ Transplantation Committee to amend lung allocation policy and effectively introduce a new lung allocation system for candidates ages 12 and older. The new system for allocating lungs uses lung transplant candidates' waitlist medical urgency and transplant benefit to determine priority for lung offers. The system would assign priority to lung candidates who are at higher risk of death if they do not receive a transplant (waitlist urgency) and who are likely to receive a greater benefit of longer lifetime with a transplant as compared to without a transplant (transplant benefit).

The new lung allocation system is scheduled for implementation on May 4, 2005. As work has progressed on the programming and implementation of the new system several issues have arisen that necessitate further clarifications in OPTN/UNOS policy 3.7.6 and 3.7.9. The proposed policy clarifications are consistent with the original concepts described in the policies approved by the Board. The proposed clarifications provide additional detail regarding or specific application for some of the general constructs found in the original policy.

The proposed policy modifications will:

- Provide greater clarification in the descriptions of the factors used to calculate the Lung Allocation Score (LAS);
- Provide more specific information about requirements for updating candidates' data and a more specific data update timeline;
- Provide more detail regarding the operation of the Lung Review Board (LRB);
- Describe in additional detail the information that is necessary to register a candidate for a lung transplant;
- Describe in additional detail situations where a candidate will be assigned a least beneficial value for a missing variable and when they will be assigned a Lung Allocation Score of zero and;
- Describe in additional detail how candidates will be prioritized in the event of tied Lung Allocation Scores.

The proposed policy clarifications/modifications are being submitted for public comment concurrent with programming and implementation on UNet[sm].

2. Policy Goals

The goals of the newly proposed modifications to lung allocation policy will remain consistent with the original goals of the lung allocation system. The lung allocation system is intended to accomplish the following goals:

1) Reduce the number of deaths on the lung transplant waiting list;

2) Increase transplant benefit for candidates who receive a lung transplant;

3) Ensure efficient and equitable allocation of lungs to active transplant candidates.

The proposed policy modifications described in this document are intended to add additional detail to the existing policy language and a greater description of how the lung allocation system will function.

3. Background and Significance

At the June 24-25, 2004 meeting of the OPTN/UNOS Board of Directors, the Board unanimously passed a resolution from the OPTN/UNOS Thoracic Organ Transplantation Committee to amend lung allocation policy and effectively introduce a new lung allocation system for candidates ages 12 and older. Subsequent to the Board's approval, the Thoracic Committee, the Lung Allocation Subcommittee, the Lung Allocation System Implementation Working Group, and staff have been working toward implementing the new allocation system. During this implementation phase, issues have arisen that required additional discussion and clarification in order to provide direction to programming staff. Some of these discussions have resulted in additional details regarding how the new system will work. We are providing these details in this document to ensure that there is transparency and a clear understanding of the system when it is implemented on May 4, 2005.

The original policy language that created the new lung allocation system included general recognition of the following features of the system:

- Lung Review Board and Lung Candidates with Exceptional Cases
- Situations where candidates are missing required data
- Entering and updating the candidate variables used to calculate the Lung Allocation Score
- Use of accumulated waiting time in the lung allocation system

On September 15, 2004, Phase I of the new lung allocation system was implemented on UNet^{sm}. Phase I allowed lung programs to begin entering data variables on their heart/lung and lung candidates to be used in the calculation of the Lung Allocation Score. Subsequent discussions regarding issues involved in the implementation of Phase I by the Thoracic Committee and the LAS Implementation Working Group (this working group is described in paragraph below) have led to suggested changes to some of the descriptions of the factors used to predict pre and post- transplant survival. On November 18, 2004, the OPTN/UNOS Board of Directors approved Lung Review Board (LRB) guidelines that provided specific descriptions of the composition and function of the LRB. Subsequent discussions regarding issues involved in the implementation of the LRB by the Thoracic Committee, the Lung Allocation Subcommittee, and the LAS Implementation Working Group also have resulted in suggested changes to lung allocation policy that incorporate additional details on the LRB review process.

On January 28, 2005, the OPTN/UNOS Thoracic Committee met to discuss the programming and implementation issues involving the new lung allocation policies. During that discussion, the Committee recognized that in the months leading up to the implementation of the lung allocation system, issues and questions may arise regarding various aspects of programming that would need immediate answers and direction in order to maintain the strict implementation schedule. To allow for the expedited resolution of these issues, the Thoracic Committee created the Lung Allocation System Implementation Working Group, consisting of the Thoracic Committee Chair, the Lung Subcommittee Chair, and a Committee member that specializes in pediatric lung transplantation. The Thoracic Committee specifically authorized the LAS Implementation Working Group to resolve any remaining issues that would arise during the implementation process and report their decisions to the Lung Subcommittee and the Thoracic Committee at future meetings.

4. Detailed Descriptions of Proposed Policy Modifications

On March 18, 2005, the LAS Implementation Working Group approved the newly proposed modifications to existing lung allocation policies. The proposed modifications described here would provide additional detailed descriptions of the general concepts that were described in the original policy. The proposed policy modifications are described as follows:

A. *Factors Used to Predict Risk of Death on the Lung Transplant Waitlist and Factors that Predict Survival After Lung Transplant*

Importantly, the actual factors that are used in the lung allocation system to predict risk of death on the lung transplant waiting list and the factors that are used to predict post-transplant survival have not changed from the factors that were originally approved. The newly proposed modifications are intended to clarify more precisely which data elements will be used in the calculation of the Lung Allocation Score.

On September 15, 2004, the first version of the data entry screens for the new lung allocation system became available on UNet^{sm}. These original data entry screens requested all of the data for the factors that the lung allocation system uses to predict waitlist urgency and post-transplant survival as they are listed in Tables 1 and 2 of existing Policy 3.7.6.1. (Candidates Age 12 and Older). On October 8, 2004, the Thoracic Committee opined that several of the fields on the data entry screens should be more specific as to the descriptions of the data that are being collected. The Committee also suggested that greater specificity and additional choices would provide data better suited for revising and improving the lung allocation system in the future.

1) **"Insulin Dependent Diabetes"** The Thoracic Committee opined that the "Diabetes" inquiry on the data entry screen should be expanded to allow more choices that encompass situations that arise in treating diabetic patients in clinical practice. The LAS Implementation Working Group later approved a change to the data entry field for "Diabetes" where the user would respond to this inquiry by choosing from the following specific answers: "Dependency unknown," "Insulin dependent," "not insulin dependent,", or "not diabetic." This change will allow for more specificity in data collected on lung transplant candidates. The first three choices will be considered as having "Diabetes" for the purposes of computing the Lung Allocation Score. On March 18, 2005, the LAS Implementation Working Group proposed a modification to Table 1 in Policy 3.7.6.1 (Candidates Age 12 and Older) that changes the name of the data variable as it appears in policy from "Insulin dependent diabetes" to simply "Diabetes."

2) **"Ventilator Use"** The Thoracic Committee opined that the "ventilator use" inquiry on the data entry screen should be expanded to allow more choices that more specifically describe the various types of assisted ventilation that lung transplant candidates may receive. The original data entry screen allowed a user to simply choose "yes" or "no" in response to the inquiry. The Committee approved a change to this data entry field from "Ventilator use" to "Assisted ventilation." The user will be allowed to choose the following descriptions of a candidate's assisted ventilation: "BiPAP," "CPAP," "Continuous mechanical," Intermittent mechanical," and "No assisted ventilation needed." Of the choices, only "continuous mechanical ventilation" will be considered "assisted ventilation" for the purpose of calculating the Lung Allocation Score. This is consistent with the data modeling that supported the original policy proposal. This change will allow for more specificity in data collected on lung transplant candidates. Accordingly, on March 18, 2005, the LAS Implementation Working Group proposed a modification to Table 1and Table 2 in Policy 3.7.6.1 (Candidates Age 12 and Older) that changes the name of the data variable as it appears in policy from "Ventilator use" to "Continuous mechanical ventilation."

3) **"Creatinine"** On March 18, 2005, the LAS Implementation Working Group approved a housekeeping modification to Table 2 in Policy 3.7.6.1 (Candidates Age 12 and Older) that changes the name of the variable "Creatinine" to "Serum Creatinine" to more accurately describe this variable. On the data entry screens, the data field will be labeled "Serum Creatinine."

B. Candidate Variables in UNet[sm]

During the programming and implementation phases of the lung allocation system, the LAS Implementation Working Group, further clarified which clinical data variables are needed in order to register a candidate for lung transplantation, or if missing, would be assigned a Least Beneficial Value or give the candidate a zero LAS. These clarifications were initially introduced to the Lung Subcommittee at the January 27, 2005, meeting, and the LAS Implementation Working Group approved the modifications as they appeared in the final programming specifications documents. The proposed modifications do not change the data entry requirements, but add extra specificity to the description of how the clinical data variables will be treated in the system and is consistent with the policies approved by the OPTN/UNOS Board of Directors in June 2004. The proposed changes to Policy 3.7.6.3 (Candidate Variables in UNet[sm]) address the following details:

1) **A lung transplant candidate's lung diagnosis, date of birth (used to calculate age), and height and weight (used to calculate body mass index) must be provided when a candidate is initially registered for a transplant or the candidate will not be allowed to register**. The LAS Implementation Working Group does not believe that it is appropriate for the system to assign a diagnosis to candidates, and therefore, believes that the transplant program must enter a diagnosis code in order to register the candidate for transplantation. Height, weight, and birth date are currently data that is required to register a candidate. The LAS Implementation Working Group opined that this requirement should not change. Therefore, if these variables are missing, the transplant center will not be allowed to register the candidate.

2) **Candidates will receive a Lung Allocation Score of zero (the lowest possible score) if the New York Heart Association classification ("NYHA class") or assisted ventilation variables are missing**. These two candidate variables appear on both the waitlist survival curve and the post-transplant survival curve of the lung allocation algorithm. Because these variables apply to both survival curves, the LAS Implementation Working Group opined that a least beneficial value could not be assigned since assigning a least beneficial value on the pre-transplant side of the model could be mitigated on the post-transplant side of the model. For this reason, it was decided that these two variables should be absolute requirements for initial registration on the wait list. Additionally, as these variables are both easily observed in clinical practice, it was felt that it would not be an additional burden on the centers to require their completion for a non-zero score.

   The concept of assigning a Lung Allocation Score of zero for missing variables was addressed in the original policy proposal and approved by the OPTN/UNOS Board of Directors. The existing policy language requires that a zero LAS will be assigned to any newly registered candidate with no data at the time of listing, or for existing lung transplant candidates with no or incomplete data at the time the lung allocation system is implemented. By assigning a zero LAS for candidates only if these two specific variables are missing, the proposed policy changes would have the effect of relaxing the data entry requirement for these candidates , and thereby reducing the possibility of disadvantaging a patient due to lack of data entry.

3) **All other candidate variables that are missing at the time a new candidate is registered for a lung transplant or subsequent to registration will receive a default value that results in the lowest contribution to Lung Allocation Score.** The existing policy provides for the replacement of missing values with default values. The proposed change clarifies the existing language by specifying exactly which missing variables will be automatically substituted with a default value. Additionally the proposed policy changes refer to the default value as the "Least Beneficial Value," the term that is used on the UNet[sm] data entry screens.

4) **Estimated values that have been approved by the Lung Review Board to be used as substitutes for unobtainable actual values will be valid until updated.** The policy currently allows transplant centers to request approval from the Lung Review Board to use estimated clinical values in the computation of the Lung Allocation Score. Estimated values are to be requested in situations where an actual value is unobtainable due to a candidate's inability to

perform a test or have a procedure necessary to obtain the value. The proposed policy change clarifies the existing policy and provides that estimated values, once approved by the Lung Review Board, will remain valid until an actual clinical value is provided or a new estimated value is requested and approved by the Lung Review Board.

C. Candidate Variables in UNet^{sm} upon Implementation of the Lung Allocation System

The proposed modifications to Policy 3.7.6.3.1 (Candidate Variables in UNet^{sm} upon Implementation of Lung Allocation Scores Described in Policy 3.7.6) would require the same data entry, described above, for candidates already registered for lung transplantation at the time this system is implemented. The existing policy requires that registered candidates with any missing clinical variables receive a Lung Allocation Score of zero. The proposed policy changes significantly relax this requirement by making existing candidates subject to the same data entry requirements as new candidates who register for transplants after the implementation of the system.

D. Updating Candidate Variables

During the programming and implementation phases of the lung allocation system, the LAS Implementation Working Group, with the authority of the Thoracic Committee, approved specific requirements for updating clinical data variables on the system and the effects of failing to update those variables. The proposed modifications do not change the data entry requirements, rather, the proposed modifications add specificity to the description of the data requirements that is found in the existing policy language. In addition, the proposed changes are specific about the effects of failing to update clinical variables on time. The proposed changes to Policy 3.7.6.2 (Updating Candidate Variables) address the following details:

1) **Variables that have not been updated since the most recent six-month "anniversary" date of the initial listing date will be considered expired.** The existing policy specifies that each candidate's clinical variables must be updated at least once every six months beginning on the date that the candidate was initially registered for a lung transplant. The proposed policy modifications offer more detail to clarify how the update schedule operates and when clinical variables will be considered expired. Additionally, the proposed policy modifications include a descriptive hypothetical example of an update schedule.

2) **Candidates will receive a Lung Allocation Score of zero if either the New York Heart Association classification data or the assisted ventilation data is expired.** As stated above, these two candidate variables appear on both the waitlist survival curve and the post-transplant survival curve of the lung allocation algorithm. If a user does not update either or both values, then it becomes much more difficult to compute a Lung Allocation Score. During the programming phase of the lung allocation system, no least beneficial default value was selected for these variables if they are expired. For this reason, it was decided that these two variables should be absolutely required to be updated at each six-month interval.

3) **All other candidate variables with expired data will receive the Least Beneficial Value for that variable.** The proposed change clarifies the existing language by specifying exactly which variables will automatically receive a Least Beneficial Values if the values provided previously expire.

4) **Candidate variables required to be obtained by heart catheterization may be updated at the discretion of the transplant center.** The existing policy language provides that variables that must be obtained with a heart catheterization do not need to be updated at six-month intervals. Instead, those variables may be updated at the discretion of the lung transplant center. The proposed policy modifications remain consistent with the existing policy language, but specify that the variables that are required to be obtained by heart catheterization are the pulmonary artery

pressures and pulmonary capillary wedge pressure. Additionally, the proposed policy modifications allow for either actual values for these variables or estimated values that have been approved by the Lung Review Board to remain valid until they are updated with a new actual value or a new estimated value is approved by the Lung Review Board.

E. The Lung Review Board and Lung Candidates with Exceptional Cases

The existing language of Policy 3.7.6.4 (Lung Candidates with Exceptional Cases) provides for the formation of the Lung Review Board to prospectively review situations where transplant candidates may have special needs or exceptional circumstances. On November 18, 2004, the OPTN/UNOS Board of Directors approved operational guidelines for a national Lung Review Board (LRB). As the implementation of the lung allocation system progressed and as the Lung Review Board was assembled and organized, the Thoracic Committee and the Lung Allocation Subcommittee approved changes to the LRB guidelines to more fully describe the procedures that the LRB must follow when reviewing requests from transplant centers. (The Lung Review Board Guidelines are included as a reference with this public comment document as Attachment A.)

Several essential features of the review process that are found in the LRB guidelines were approved to be added to the existing language of Policy 3.7.6.4 (Lung Candidates with Exceptional Cases) to fully describe the review process and to give greater authority to these policy provisions. The proposed modifications to Policy 3.7.6.4 (Lung Candidates with Exceptional Cases) address the following details:

1) **Transplant programs may request approval of estimated values, diagnoses, or a specific Lung Allocation Score.** This proposed policy modification specifies the types of requests that may be submitted to the LRB.

2) **Timeframe for reviews by the Lung Review Board.** The proposed policy modifications describe the time frames for case review by the LRB and the effect if a review is not conducted during the required period of time. The LRB will have seven days to reach a decision on initial requests sent to it from transplant centers. If an initial request is denied, then the transplant center will have seven days from the date of the denial to appeal the LRB's decision. The LRB will then have seven days to review the appeal. If the LRB has not completed its review of an initial request or an appeal within seven days, then the transplant center will receive the Lung Allocation Score, estimated value, or lung diagnosis it requested, and the center's request will be automatically referred to the OPTN/UNOS Thoracic Organ Transplantation Committee for further review.

3) **Estimated values that are approved by the Lung Review Board or the Thoracic Committee remain valid until an actual value is entered in the system or a new estimated value is approved.**

4) **Diagnoses that are approved by the Lung Review Board will remain valid indefinitely or until an adjustment is made and, if necessary, approved by the LRB**.

5) **Lung Allocation Scores that have been requested by transplant centers and approved by the Lung Review Board will remain valid for six months**.

F. Use of Accumulated Waiting time in the Lung Allocation System

As programming on the new lung allocation system has progressed, a situation was identified that may increase the possibility of tied Lung Allocation Scores. While it is still highly unlikely that there will be tied Lung Allocation Scores for candidates with all clinical variables provided, there is a possibility of tied scores where the Lung Review Board has approved a center's request for a numerical modification to a candidate's existing Lung Allocation Score (exceptional case review) or where many of the clinical factors are missing and Least Beneficial Values are used instead.

In an early discussion of how to further stratify lung transplant candidates where there are tied scores, the Lung Allocation Subcommittee opined that the new system was designed to minimize the use of waiting time, and that the inclusion of waiting time in the new system would encourage the continuation of the practice of adding candidates to the waitlist as early as possible and perhaps before the program was willing to accept a lung offer for the candidate. The Subcommittee recommended that in the event of multiple candidates receiving the same priority for an organ due to a tied Lung Allocation Score, a computer-generated random number should be generated to break the tie. The Subcommittee agreed to revisit the issue after implementation if tied Lung Allocation Scores occur more frequently than originally expected.

To clarify the method of breaking ties among candidates with identical priority for lung offers due to identical Lung Allocation Scores, the following modification to UNOS Policy 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), was proposed for approval by the OPTN/UNOS Executive Committee:

> **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.** 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 and thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by random number selection performed by the UNOS organ matching system.

On March 11, 2005, the Executive Committee discussed this issue and decided that policy should not use a random number to determine priority among tied Lung Allocation Scores. Instead, ties would be decided by the total amount of waiting time accumulated by the candidates. The Executive Committee reasoned that the existing policy allows for waiting time to break ties among candidates with Lung Allocation Scores of zero. The Executive Committee was reluctant to depart from this method of tie-breaking in favor of another method without the proposal first being submitted for public comment. The following policy language was approved for implementation concurrent with public comment:

> **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.** 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 and thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.

Registered lung candidates would not accumulate waiting time while waiting at inactive status, but would be subject to the same requirements for data entry and updates as candidates registered at active status.

5. Future Policy Considerations

On April 14, 2005, the OPTN/UNOS Executive Committee met to discuss additional policy modifications that may be considered for implementation in the future. The discussion stemmed from alternative ideas presented by the Lung Allocation System Implementation Working Group that were not considered in the original policy proposal, but, if implemented, would be expected to have an impact on the operation of the lung allocation system. The Executive Committee specifically invites public comment on the following issues:

- Candidates with Lung Allocation Scores of zero will automatically be assigned inactive status and will not receive offers for donor lungs
- Alternative methods of determining priority among candidates with tied Lung Allocation Scores and identical priority for lung offers
- Prospective review of requests sent to the Lung Review Board and the ability of transplant programs to override LRB decisions

*****Public comment with respect to these matters is strongly encouraged.*****

A. Proposed: Candidates with Lung Allocation Scores of Zero will be Automatically Downgraded to Inactive Status

The modified lung allocation policy and new policy modifications proposed in this document acknowledge the circumstances under which lung transplant candidates will receive Lung Allocation Scores of zero. In the original policy, a Lung Allocation Score of zero would be assigned to candidates, who at the time the system is implemented, have no candidate data or incomplete date entered on the UNet[sm] system. The proposed modifications change this requirement by assigning a zero Lung Allocation Score only to those candidates who have two specific candidate variables that are missing or expired: “NYHA classification” or “assisted ventilation.”

Recent recommendations from the Executive Committee and the LAS Implementation Working Group would assign inactive status to all candidates with zero Lung Allocation Scores. Both assisted ventilation use and NYHA classification are effective measures of functionality in lung transplant candidates, and are also significant predictors of both waitlist urgency and post-transplant survival. The LAS Implementation Working Group has suggested that without updated information for these two variables, there is not sufficient information to make an organ offer. The Executive Committee concurred. Further, it was suggested that if there are a high number of candidates registered for transplantation who receive zero Lung Allocation Scores, this is an indicator that centers may not be updating data for candidates they do not believe are ready to receive organ offers. In addition, the Executive Committee and the LAS Implementation Working Group concurred that if candidates with zero Lung Allocation Scores are not ready for transplantation, then it would be a waste of valuable organ placement time if these candidates appeared on match runs and received organ offers only to have those offers declined by the transplant centers.

For the reasons above, the Executive Committee and the LAS Implementation Working Group proposed that candidates with Lung Allocation Scores of zero be automatically placed in inactive status, with no accrual of waiting time, and ineligible to receive organ offers. This proposal has not been programmed on the UNet[sm] system and is not being implemented at this time because it is a departure from the prior lung policy proposals and should receive input through the public comment process. **However, the outcome of the discussion between the Executive Committee and the LAS Implementation Working Group was that, prior to the implementation of the lung allocation system on May 4, 2005, transplant programs would be notified of any candidates on their waiting lists who will receive a zero Lung Allocation Scores because of data that is currently missing or expired. Further, these programs would be**

advised of the opportunity to voluntarily inactivate these candidates if the program would not accept an organ offer for them when available.

B. Proposed: Alternative Methods of Breaking Ties among Lung Allocation Scores

The Executive Committee and the LAS Implementation Working Group also have engaged in dialogue about the predicted frequency of tied Lung Allocation Scores among candidates and an effective method of breaking those ties. As indicated in Section 4.F. of this document, the Executive Committee approved a policy modification that would allow ties to be decided by assigning priority to the candidate with the most total accrued waiting time. The concept of using waiting time to break ties was included in the original policy proposal to decide cases of ties among candidates with Lung Allocation Scores of zero, and the Executive Committee, when presented with the possibility that ties may occur among candidates with scores greater than zero, opted to continue with this method until a more effective method could be found.

It should be noted that the original policy proposal circulated for public comment in March 2004, contained a discussion of the use of waiting time to break ties among Lung Allocation Scores of zero. That original proposal acknowledged that the use of waiting time to decide these cases would be a temporary measure until the mechanism for deciding ties could be re-evaluated. The Executive Committee's discussion of this issue and subsequent proposal are consistent with this provision of the original lung allocation policy proposal.

1) **Ties among candidates with Lung Allocation Scores of Zero.** As indicated above, the Executive Committee and the LAS Implementation Working Group have proposed candidates that receive Lung Allocation Scores of zero should be automatically downgraded to inactive status. If candidates with Lung Allocation Scores of zero are inactive, then they will not receive lung offers, and there will be no need to break ties among their scores or otherwise decide priority among them.

2) **Ties among candidates with Lung Allocation Scores greater than Zero**. Because candidates' Lung Allocation Scores are computed to 34 decimal places, it is expected that tied scores will be rare. The possibility that two candidates will have identical priority for the same lung allocation offer becomes even more remote when one considers that two candidates must have identical Lung Allocation Scores, identical ABO type, and the same geographic proximity to the donor hospital. Nonetheless, the possibility of ties exists and becomes more likely among candidates who have been assigned Least Beneficial Values to replace missing data.

   In situations where multiple candidates have identical priority for lung offers, the Executive Committee and the LAS Implementation Working Group have proposed as an alternative to the tiebreaker proposal in Section 4.F. that the priority for these candidates to receive organs offers be determined by the date of each candidate's most recent data update on UNet^sm^. For example, consider a situation where two candidates have identical priority for a lung offer resulting from tied Lung Allocation Scores and other identical factors. If Candidate A's data variables were last updated on March 10, 2005, and Candidate B's data variables were last updated on April 10, 2005, then Candidate A would receive the higher priority for the offer because his most recent data update occurred first.

3) **Ties among candidates with Lung Allocation Scores assigned to them by the Lung Review Board**. The original policy proposal generally described the concept of a lung review board that would make decisions in special cases where a candidate's transplant team believes that a candidate's Lung Allocation Score may not reflect exceptional circumstances regarding that candidate's medical condition. As the Lung Review Board was organized, operational guidelines and policy modifications were proposed that allowed the Lung Review Board to assign a specific Lung Allocation Score to these candidates upon request by the transplant program. This feature of the lung allocation system raises the possibility that the Lung Review Board may approve multiple requests to assign the same, whole integer Lung Allocation Score to multiple candidates.

The Executive Committee and the LAS Implementation Working Group have proposed that, in the situation where multiple candidates have identical priority for a lung offer due to tied Lung Allocation Scores assigned to them by the LRB, and other identical allocation factors, then priority for the lung offer should be decided by the earliest date and time that the LRB's decision was entered on UNet^{sm}. For example, consider a situation where both Candidate A and Candidate B have Lung Allocation Scores of 33 assigned to them by the LRB and identical priority to receive a lung offer. The tie between Candidate A and Candidate B would be decided by the earlier of the two dates that the LRB entered the decision to assign them each that score on UNet^{sm}. Therefore, if the LRB entered the decision for Candidate A on May 10, 2005, and the decision for Candidate B was entered on June 10, 2005, then Candidate A would receive higher priority for the lung offer because his Lung Allocation Score was approved by the LRB first.

C. Proposed: Transplant Programs may Override Lung Review Board Decisions if Necessary

During the discussion between the OPTN/UNOS Executive Committee and the LAS Implementation Working Group on April 14, 2005, the issue of prospective review by the LRB and transplant programs' ability to override LRB decisions was raised. The original policy proposal that was approved by the OPTN/UNOS Board of Directors on June 25, 2004, contained a provision in Policy 3.7.6.3 that allowed transplant programs to override default values ("Least Beneficial Values") that may be assigned to lung candidates when their data is missing, and instead enter estimated data that the treating physicians deem to be medically reasonable. Originally, cases where this override feature was used would be referred to the Thoracic Organ Transplantation Committee for retrospective review to determine if the value(s) entered is appropriate. The original policy proposal also included a provision in Policy 3.7.6.4 that required special (exceptional) cases to be reviewed by the Lung Regional Review Board.

On November 18, 2004, the OPTN/UNOS Board of Directors approved a modification to Policy 3.7.6.3, proposed by the Thoracic Committee and submitted for public comment, that would strike this override provision, and replace it with new policy language that would require the newly formed Lung Review Board to prospectively review and approve transplant programs' requests to use estimated values prior to entering these values on UNet^{sm}. The Board of Directors also approved a modification to Policy 3.7.6.4 that requires prospective review of special cases by the Lung Review Board. In addition to the policy modifications, the Board of Directors approved proposed operational guidelines for the Lung Review Board that also required prospective review of transplant programs' requests to use estimated values and requests for special case review.

During the implementation and programming phases of the lung allocation system, OPTN/UNOS's legal counsel recommended to the OPTN/UNOS Executive Committee that the lung allocation policies be modified to allow transplant programs to override decisions of the Lung Review Board if the treating physicians do not agree with the LRB's decision. By overriding the LRB's decision, the transplant program would consent to having the request automatically referred to the OPTN/UNOS Thoracic Committee for peer review. It has been suggested that by requiring prospective review by the LRB, but not allowing the centers to override the LRB's decision if it is adverse to the transplant program's request, then the review process has the effect of undermining the judgment of the treating physician with regard to the patient under his or her care. This would, in effect, substitute the medical judgment of the treating physician for the judgment of the Lung Review Board who have no actual clinical experience with that transplant candidate. In addition, experience with exceptional case prospective review in heart and liver allocation has demonstrated that providing for overrides by the treating physician aids the process of policy refinement.

The OPTN/UNOS Executive Committee acknowledged the validity of these concerns, and agreed to discuss the issue further at a future meeting. In the interim, the Committee agreed to submit this discussion for public comment and offer a suggestion for policy modifications that would continue to require prospective LRB review of requests, but allow transplant programs to override adverse decisions of the LRB if the treating physician deems it necessary, and have override requests referred automatically to the

Thoracic Committee for peer review. The suggested policy modifications are included in Section 7 at the end of this document.

6. Policy Proposal

The following policy modifications were approved by the Lung Allocation System Implementation Working Group (with the authority of the Thoracic Committee) and the OPTN/UNOS Executive Committee to be submitted for public comment concurrent with implementation and programming on the UNet[sm] system:

RESOLVED, that the following proposed modifications to Policies 3.7.6 (Lung Allocation) and Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates) be submitted for public comment concurrent with implementation and programming on the UNet[sm] system (Due to time constraints, the Executive Committee was unable to fully consider and formally vote on the matter of Lung Review Board prospective review without the ability to override the LRB decision by the program. The Executive Committee will take up the matter at its next meeting):

3.7.6 **Lung 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

i. Forced vital capacity (FVC)
ii. Pulmonary artery (PA) systolic (Group A, C, D[1])
iii. O_2 required at rest (A, C, D[1])
iv. Age
v. Body mass index (BMI)
vi. Diabetes ~~Insulin dependent diabetes~~
vii. Functional status (New York Heart Association (NYHA) class)
viii. Six-minute walk distance
ix. Continuous mechanical ventilation ~~Ventilator use~~
x. 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[1])
2. PCW pressure ≥ 20 (Group D[1])
3. Continuous mechanical ventilation ~~Ventilator use~~
4. Age
5. Serum 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

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. Diagnosis, birthdate (used to calculate age), height, and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. ~~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.~~ Candidates will receive a Lung Allocation Score of zero, the score with the lowest priority, if the New York Heart Association class or assisted ventilation variable is missing at any time. If any other candidate variables are missing, then a default value, which will be the ~~The~~ value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), 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. **Prior to entering such estimated values, programs must request review and approval from the Lung Review Board**~~**Use of the override feature results in an automatic review by the Thoracic Organ Transplantation Committee**~~ to determine whether the ~~**override**~~ **estimated** values ~~**selected**~~ are appropriate and whether further action is warranted. Estimated values that have been approved by the Lung Review Board will remain valid until those values are either updated with an actual value or a new estimated value is requested and approved by the Lung Review Board.

*******BOLD** *language that appears in Policy 3.7.6.3 indicate policy changes that were released for public comment in August 2004, and later approved by the OPTN/UNOS Board of Directors in November 2004.*

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 the Least Beneficial Value for each incomplete variable or a Lung Allocation Score of zero, the score with the lowest priority, as described in Policy 3.7.6 above.

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. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month "anniversary" is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)

If the New York Heart Association class or assisted ventilation variable is expired, then the candidate will receive a Lung Allocation Score of zero. If any other candidate variable is expired, then the candidate will receive the Least Beneficial Value for that variable. The frequency of updating those candidate variables that are ~~obtainable only~~ required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) will be left to the discretion of the transplant center. Actual values or approved estimated values for pulmonary pressures will be valid until they are either updated with a new actual value or a new estimated value is requested and approved by the Lung Review Board

3.7.6.4 **Lung Candidates With Exceptional Cases**. Special cases require **prospective** review by the Lung ~~**Regional**~~ Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to UNOS. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that UNOS sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that UNOS sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the OPTN/UNOS Thoracic Organ Transplantation Committee for further review.

Requested estimated values that have been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee will remain valid until an actual value is entered in the system or a new estimated value is requested and is approved by the Lung Review Board. A diagnosis that has been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Requested Lung Allocation Scores that have been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee will remain valid for six (6) months from the approval date. If the candidate continues to be on the waiting list six months after the approval date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is approved by the Lung Review Board or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung **Review Board** ~~**RRB's**~~.

****BOLD** *language that appears in Policy 3.7.6.4 indicate policy changes that were released for public comment in August 2004, and later approved by the OPTN/UNOS Board of Directors in November 2004.*

******NO CHANGES TO POLICY 3.7.7 AND 3.7.8******

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, 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 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 **and thereafter** will be used to determine priority in lung allocation among

candidates with Lung Allocation Scores of zero. **In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued**. Candidates awaiting a lung transplant on the UNOS Patient Waiting List that are placed at inactive status by the listing center will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

******BOLD** language that appears in Policy 3.7.9.2 was approved by the OPTN/UNOS Executive Committee on March 11, 2005.*

******NO PROPOSED CHANGES TO POLICY 3.7.11 (SEQUENCE OF ADULT DONOR LUNG ALLOCATION) OR POLICY 3.7.11.1 (SEQUENCE OF PEDIATRIC DONOR LUNG ALLOCATION)***

****** END OF PROPOSED POLICY MODIFICATIONS***

7. Future Policy Considerations – Suggested Policy Modifications

The following policy modifications have been discussed in response to the concerns addressed in Section 5 (Future Policy Considerations) concerning prospective Lung Review Board review of requests for estimated values and specific Lung Allocation Scores and transplant programs' ability to override LRB decisions. **The suggested policy modifications in this section are not being implemented concurrent with public comment.** Rather, the OPTN/UNOS Executive Committee and the Thoracic Committee are seeking input from the transplant community on these suggestions and their place in future improvements to lung allocation policy.

The following policy modifications have been suggested:

****** NO SUGGESTED POLICY MODIFICATIONS TO POLICY 3.7.6.1 AND 3.7.6.2 ******

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. Diagnosis, birthdate (used to calculate age), height, and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. ~~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.~~ Candidates will receive a Lung Allocation Score of zero, the score with the lowest priority, if the New York Heart Association class or assisted ventilation variable is missing at any time. If any other candidate variables are missing, then a default value, which will be the ~~The~~ value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), 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. **Prior to entering such estimated values, programs must request review and approval from the Lung Review Board** ~~**Use of the override feature results in an automatic review by the Thoracic Organ Transplantation Committee**~~ to determine whether the ~~**override**~~ **estimated** values ~~**selected**~~ are appropriate and whether further action is warranted. Estimated values ~~that have been approved by the Lung Review Board~~ will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to the procedures set forth in Policy 3.7.6.4.~~requested and approved by the Lung Review Board.~~

***BOLD *language that appears in Policy 3.7.6.3 indicate policy changes that were released for public comment in August 2004, and later approved by the OPTN/UNOS Board of Directors in November 2004.*

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 the Least Beneficial Value for each incomplete variable or a Lung Allocation Score of zero, the score with the lowest priority, as described in Policy 3.7.6 above.

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. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month "anniversary" is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)

If the New York Heart Association class or assisted ventilation variable is expired, then the candidate will receive a Lung Allocation Score of zero. If any other candidate variable is expired, then the candidate will receive the Least Beneficial Value for that variable. The frequency of updating those candidate variables that are ~~obtainable only~~ required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) will be left to the discretion of the transplant center. Actual values or ~~approved~~ estimated values for pulmonary pressures will be valid until they are either updated with a new actual value or a new estimated value is ~~requested and approved by the Lung Review Board~~ entered pursuant to Policy 3.7.6.4.

3.7.6.4 Lung Candidates With Exceptional Cases. Special cases require **prospective**

review by the Lung ~~**Regional**~~ Review Board Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to UNOS. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that UNOS sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that UNOS sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the OPTN/UNOS Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant center's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant center has the option to override the decision of the LRB. If the transplant center elects to override the decision of the Lung Review Board, then the request or appeal will automatically referred to the OPTN/UNOS Thoracic Organ Transplantation Committee for review.

~~Requested~~ Estimated values ~~that have been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee~~ will remain valid until an actual value is entered in the system or a new estimated value is entered pursuant to the procedures described in this policy. ~~.requested and is approved by the Lung Review Board~~. A diagnosis that has been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. ~~Requested~~ Lung Allocation Scores ~~that have been approved by the Lung Review Board or the OPTN/UNOS Thoracic Organ Transplantation Committee~~ will remain valid for six (6) months from the ~~approval~~ entry date. If the candidate continues to be on the waiting list six months after the ~~approval~~ entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy. ~~approved by the Lung Review Board~~ or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung **Review Board** ~~**RRB's**~~.

*****BOLD** *language that appears in Policy 3.7.6.4 indicate policy changes that were released for public comment in August 2004, and later approved by the OPTN/UNOS Board of Directors in November 2004.*

******NO SUGGESTED CHANGES TO POLICY 3.7.7 AND 3.7.8******

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, 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 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 **and thereafter** will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. **In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores ~~that have been approved by the Lung Review Board~~ pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued**. Candidates awaiting a lung transplant on the UNOS Patient Waiting List that are placed at inactive status by the listing center will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

******BOLD** language that appears in Policy 3.7.9.2 was approved by the OPTN/UNOS Executive Committee on March 11, 2005.*

******NO SUGGESTED PROPOSED CHANGES TO POLICY 3.7.11 (SEQUENCE OF ADULT DONOR LUNG ALLOCATION) OR POLICY 3.7.11.1 (SEQUENCE OF PEDIATRIC DONOR LUNG ALLOCATION)***

Attachment A – Lung Review Board Operational Guidelines

UNOS NATIONAL LUNG REVIEW BOARD OPERATIONAL GUIDELINES

1. **Purpose**

The purpose of the Lung Review Board (LRB) is to provide prompt prospective peer review of requests from listing transplant centers on behalf of their candidates on the OPTN Waiting List for estimated clinical values, diagnosis and exceptional scores.

2. **Board Composition**

A. The Lung Review Board is composed of seven individual lung transplant surgeons or lung transplant physicians and a pediatric member with an ad hoc pediatric member randomly selected from a national pool of active lung transplant programs that have agreed to participate on the LRB. Seven Lung Review Board members represent active adult lung transplant programs and one member represents an active pediatric lung transplant program. The pediatric member will only be sent cases involving pediatric lung transplant candidates. The chair of the OPTN/UNOS Thoracic Organ Transplantation Committee (the committee) shall appoint a primary LRB member from among those selected to serve as the Lung Review Board Chair for a two-year term.

B. Lung Review Board members serve a term of two years. Service terms will be staggered among the Lung Review Board members to ensure that at no time more than four terms will end. This requirement is to preserve the continuity of the LRB and the efficiency of its operation.
Initial terms upon establishment of the Lung Review Board will be four members with two year terms and four members with a term of one year. The Chair of the OPTN/UNOS Thoracic Organ Transplantation Committee will determine the terms, consistent with this requirement, for the initial LRB composition.

C. Each LRB member is required to appoint an alternate representative from his or her center. In addition to the primary pediatric LRB member and his or her alternate, there will be an alternate ad-hoc pediatric member from another transplant center who will also be required to have an alternate. This will ensure that if a case from the primary pediatric member's center requires review there will still be an opportunity for a pediatric member to review the case without a conflict of interest.

D. It is the responsibility of each member center to provide UNOS with the contact information for the both the primary LRB representative and the alternate from their center to the UNOS Membership Department. Should a representative leave his or her transplant center, then the center's alternate representative will become the representative and another alternate will be appointed. The departing member is no longer a member of the LRB.

3. **Representation**

A. Each member has one vote on each case that he or she reviews. The pediatric LRB member will be sent every case and may vote regardless of the age of the candidate.

B. Each active lung transplant program shall have the opportunity to rotate onto the review board. Rotation of the LRB will proceed as outlined above in Section 2.

C. If a member center withdraws or inactivates its lung program, it is no longer entitled to representation on the review board. The term of the member center's representative on the review board ends upon withdrawal or inactivation. Another eligible member center will be contacted at random and requested to put forth a representative and an alternate to replace the departed member. Should a program reactivate, the member center shall again have the opportunity to be represented on the Lung Review Board during future rotations.

4. **Responsibilities of the Lung Review Board Members**

A. Vote within 72 hours on all estimated clinical values entered as proxy for non-obtainable clinical diagnostic values and/or a specific diagnosis.

B. Vote within 72 hours on all exceptional cases in which a center has requested a numerical adjustment to a candidate's Lung Allocation Score.

C. Participate on conference calls as they are scheduled.

D. The alternate will vote if the member does not cast his or her vote within 72 hours. Once the alternate has been contacted to vote, the vote of the member will no longer be counted. Alternates will be contacted by UNOS staff if they are needed to review a case and cast a vote on it.

5. **Voting Procedures**

A. **Prompt Review of Estimated Clinical Values**

The Lung Review Board will prospectively evaluate the appropriateness of estimated clinical values when actual clinical values cannot be obtained prior to a candidate's listing. As soon as a majority vote of the Lung Review Board is established, the listing center will be notified whether its request was approved or denied. If the LRB has not completed its review of the listing center's request within seven (7) days of receipt, the patient will receive either the requested score or the estimated clinical value(s) and/or the specific diagnosis and the case will be forwarded on to the OPTN/UNOS Thoracic Organ Transplantation Committee. If the Lung Review Board finds the estimated clinical values requested by the listing center are appropriate, then the requested estimated clinical values may be used in calculating that candidate's Lung Allocation Score. If the values are not found to be appropriate by the Lung Review Board, the listing center may appeal the decision as outlined in Section E. A written declaration of the intention to appeal must be received by UNOS staff within seven days of receiving a negative or indeterminate decision. During the interim, the candidate's Lung Allocation Score will be calculated with the least beneficial values in place of the values being evaluated by the LRB.

B. **Prompt Review of Exceptional Cases**

The review of exceptional cases where the Lung Allocation Score is in dispute will also be conducted prospectively. The request and accompanying information will be submitted to UNOS staff from the listing center and subsequently provided to the Lung Review Board. The review will address both the appropriateness of the existing Lung Allocation Score and the appropriateness of any remedy requested by the listing center. This includes the adjustment of a candidate's Lung Allocation Score. If the LRB has not completed its review of the listing center's request within seven (7) days of receipt, the

patient will receive the requested score and the case will be forwarded on to the OPTN/UNOS Thoracic Organ Transplantation Committee.

C. **Majority Vote**

A majority vote of the Lung Review Board is required to approve all requests from transplant centers. A majority vote is calculated by dividing the total number of eligible review board members on each case by half and then adding one. In the result of a tie of the Lung Review Board votes, the decision will be handled as a denial of the request.

D. **Appeals**

A listing center may initiate an appeal if it is not satisfied with the decision of the Lung Review Board. The listing center must first fax additional information to UNOS staff supporting the request addressing the comments of dissenting LRB members. UNOS staff will then distribute this additional information to the Lung Review Board to be voted on again by the members. If this does not yield a desired outcome, the listing center may then request an appeal by conference call.

When Lung Review Board votes are counted for decisions on requests for estimated values, allocations scores, special cases and appeals the vote of a LRB member on cases originating from the member's transplant program or centers where he/she has an affiliation will be excluded from the final vote count. Should a case come from the pediatric center that is represented on the LRB be submitted for review, that case shall be forwarded to the pediatric ad-hoc review board member who is from another member center. This will provide an opportunity for a pediatric physician to review all pediatric cases without creating a conflict of interest. When a majority vote is obtained from the LRB or a case is closed, the listing center will be notified of the decision by UNOS staff. If the LRB has not completed its review of the listing center's appealed request within seven (7) days of receipt, the patient will receive the requested score or estimated value and the case will be forwarded on to the OPTN/UNOS Thoracic Organ Transplantation Committee.

The listing center may make a final appeal to the OPTN/UNOS Thoracic Organ Transplantation Committee if a satisfactory conclusion can not be met at the LRB level. Any additional information that the listing center wants the committee to consider must be faxed to UNOS staff. The Lung Review Board may also refer a case to the committee. Case referrals to the committee will include written information about the number of previous case referrals from that center and the outcome of those referrals.

A written declaration of the intention to appeal must be received by UNOS staff within seven days of receiving a negative or indeterminate (tie vote) decision. The opportunity to appeal will be terminated after seven days has passed.

Individual patients are not eligible to appeal board rulings. Only member centers may submit applications and appeals.