1. **Align VCA Program Membership Requirements with Other Programs**
   The American Society of Transplantation supports the proposal as written with no further comment.

2. **Modifications to the Distribution of Deceased Donor Lungs**
   The American Society of Transplantation is generally supportive of the proposal in concept, and offers the following comments.

   The SRTR modeling compared the previous policy (by DSA) and the current policy (by 250 nautical miles) and revealed overall similar transplant rates, waitlist mortality rates and post-transplant mortality rates.

   However, based on the simulated modeling by the SRTR, these proposed changes in this policy may impact the demographics of lung transplant candidates who are favored for receiving a lung transplant (diagnosis Group D, LAS scores >40). In addition, there may be an unfavorable impact on certain OPTN regions and small volume lung transplant centers.

   Continued analysis of the actual impact of these changes will need to be assessed in order to ensure efficient and equitable allocation of lung donor organs.

3. **Clarify Informed Consent Policies for Transmittable Disease Risk**
   The American Society of Transplantation supports the proposal in concept and offers the following comments:

   Overall, we agree that the proposed changes remove ambiguity in order to optimize the donation process, minimizing undue burdens regarding informed consent for commonly positive (or mismatched) serologies. These should be discussed under the umbrella of “routine pre-transplant education.” The AST acknowledges that discussions regarding donor disease transmission should occur early in the evaluation process as well as at the time of availability of the donor.

   1. Should informed consent policy include an actual patient signature or is discussion and medical record documentation sufficient?

      Various constituencies within AST have differing opinions as to whether actual patient signature should be mandated or whether documentation of counseling in the medical record would be sufficient. This lack of consensus within our community likely reflects a national lack of consensus regarding this topic. As such, AST suggests that it is likely best for the policy proposal from DTAC to not specify whether signature on informed consent is necessary and to leave that decision to individual transplant centers with documentation of pre-transplant education addressing these issues to be the minimum standard acceptable. Legitimate arguments can be made that adding more paperwork and signatures for patients creates more barriers to completion of an already complicated and extensive process of pre-transplant education and ultimately does not streamline
the process. Policy language does need to be broad and should address the uncertainty in transplant. Patients and their families should be educated about this uncertainty during the listing process.

2. Do you have any concerns or comments about the list of conditions in the current candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-execute the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) policies?

The majority of AST constituencies were comfortable with limiting CMV preferences to Intestinal candidates.

The Kidney Pancreas Community of Practice did express concern that although the risk of serious CMV illness is much less in other organ recipients compared to intestine recipients, the total number of CMV mismatched transplants in other organs is likely substantially high and poor outcomes such as resistant CMV disease and CMV-induced blindness should not be minimized. As such consideration of whether the CMV refusal option should be maintained in place for all organs is suggested.

4. **Concept Paper on Expedited Organ Placement**

The American Society of Transplantation supports the proposal in concept and offers the following comments:

The AST agrees that policies and guidelines should be developed to guide the expedited placement of donor livers at risk for discard (marginal organs). The expedited allocation system should identify donors as “potential expedited placement donors” when they possess specific profile characteristics of expedited donors (e.g., age >65, BMI >35, DCD) early in the process and prior to procurement, in order to alert potentially interested centers as well as the local programs that donor acceptance and utilization is under significant time constraints. Once a liver is declined in the OR, the OPO should trigger an expedited placement using a standardized pathway or guidelines that utilizes a list of liver transplant programs profiled to accept organs under these conditions. The list should focus on center acceptance criteria and historical acceptance patterns rather than an “expedited list” of patients who wish to accept such organs. Furthermore, OPTN should establish clear parameters regarding the placement process and specific timelines for decisions by the primary and backup centers when evaluating marginal organs. Emphasis should be placed on assessment of organ quality and utilization decisions made prior to cross clamp whenever possible. A time limit (e.g., 1 hour from cross clamp) should be implemented on the primary center for a decision to allow for expeditious placement with other vetted centers. Subsequent “expedited centers” should be contacted in parallel when feasible and limited evaluation time allotted per center.
The recommended pre-procurement trigger for expedited placement (within 2-3 hours prior to organ recovery) will have some benefits as well. This process of having a back-up accepting program for expedited placement prior to procurement is likely more efficient than offering the organ back to the list if turned down by the accepting program. In addition, the triggers should be in place for high-risk donors who become hemodynamically unstable or donor livers that are considered “marginal” as described above.

Transplant programs with clear past acceptance practices for organs at risk of discard will be included in the eligible programs for expedited placement, and programs without track records may be considered but should be audited regularly to determine their actual participation. Expedited placement requires rapid assessments in short periods of time, and participation of programs in the process that do not put their commitment in practice will simply delay the process and increase the risk of graft dysfunction after transplant. Some metrics regarding center specific behavior should be developed and monitored to determine which centers are more likely to transplant these “marginal organs”. This strategy will likely decrease the time for organ allocation and increase likelihood of transplant so that the utilization of these potentially discarded organs is optimized.

The development of an expedited placement policy with specific guidelines will provide more transparency for the placement of these organs. Importantly, outcomes of the organs placed expeditiously should be monitored along with other logistics as such as time to placement, costs, etc. We recommend instituting a program for both data monitoring and sharing of best practices for marginal liver grafts allocated under an expedited program. The Collaborative Innovation and Improvement Network (COINN) implemented by the OPTN to evaluate high KDPI kidney utilization provides an excellent model for a similar program.

5. Reduce Reporting Burdens and Clarify Policies on Extra Vessels
The American Society of Transplantation supports this proposal and offers the following comments and questions;

The Society applauds the proposed changes that will allow tracking of vessels and decrease burden on staff and centers by doing away with the justification requirement. This will decrease unnecessary administrative burden.

We agree that only HIV, HBV and HCV serology and NAT results be listed on the hard copy, as these will be pertinent to deciding whether to use the vessels in an urgent situation. The scan code will allow review of the remaining ID tests without crowding the label. Will labels be automatically populated with testing results or will manual entry be required?

We recommend that the current roster of infectious disease testing be maintained, with flexibility for each OPO to determine what additional infections should be tested based on the prevalence of specific infections from the specific donor location or travel history. Many OPOs are performing targeted (or sometimes universal) testing of donors with
Strongyloides antibody, Chagas antibody and West Nile Virus serology or PCR. Strongyloides results should be added to the DonorNet Infectious Diseases section.

When events are reported to DTAC, information about extra vessels should also be included in the notification.

6. Guidance on Optimizing VCA Recovery from Deceased Donors
   The American Society of Transplantation supports the proposal as written with no further comment.

7. Review Board Guidance on HCM and RCM Exceptions
   The American Society of Transplantation is supportive of the proposal, and offers the following comments:

   This proposal includes the following patients: HCM with NYHA Class IV heart failure, primary restrictive cardiomyopathy of idiopathic or genetic origin, infiltrative (e.g. cardiac amyloidosis [TTR or AL]) and radiation RCM.

   We believe that heart transplant patients who develop severe restrictive cardiac physiology, mostly due to underlying small vessel transplant coronary artery disease, should also be placed into this group. These patients with severe restrictive cardiac physiology were included in the most severe category of the ISHLT nomenclature of cardiac allograft vasculopathy, CAV-3 1. The reason for inclusion of this patient population was that mortality was high for this population 2,3. The restrictive criteria listed in this ISHLT paper (below) is similar to the criteria in this UNOS proposal for HCM/RCM patients.

   "Restrictive cardiac allograft physiology is defined as symptomatic heart failure with echocardiographic E to A velocity ratio >2 (>1.5 in children), shortened isovolumetric relaxation time (_60 msec), shortened deceleration time (>150 msec), or restrictive hemodynamic values (Right Atrial Pressure >12mmHg, Pulmonary Capillary Wedge Pressure >25 mmHg, Cardiac Index <2 l/min/m²) 1"

   For these reasons, we believe that heart transplant patients who develop severe restrictive cardiac physiology should be included with HCM/RCM patients in this UNOS proposal.

References:

8. **Changes to Waiting Time Criteria for Kidney-Pancreas Candidates**

The American Society of Transplantation supports the proposal in concept, but offers a strong recommendation that results be monitored closely after implementation. There is concern that previously small numbers available for analysis may have been underpowered to detect adverse outcomes on single kidney alone and pediatric candidates.

9. **Modify Lung TRF to Improve Post Transplant Lung Function Data**

The American Society of Transplantation supports the proposal and offers the following comments:

This step was taken to address incorrect interpretations and changing definitions of CLAD over time. Collecting raw data will allow the OPTN or SRTR to use current definitions to accurately follow the prevalence of CLAD. It is natural that the state-of-the-art in disease phenotyping will not be represented in UNOS policy. Nevertheless, restrictive allograft syndrome (RAS) has been widely employed for more than five years - and it is now considered relevant to diagnosis, prognosis, and treatment -- but it has not been captured in previous policy. This is a welcomed advancement.

The AST requests that the subcommittee consider other ways to add phenotypic specificity to the evaluation of chronic rejection: the phenomenon of “azithromycin responsive” CLAD (or NRAD, neutrophilic reversible allograft dysfunction) has likewise been accepted in clinical practice for years without being incorporated into the contemporary data collection paradigm.

The current recommendations regarding time intervals seem reasonable. Nevertheless, the AST would also ask that the subcommittee consider future incorporation of plethysmography into this data collection: we have not definitively established that spirometry is sufficient, in all cases, to distinguish RAS. Being able to make the diagnosis of RAS without plethysmography at every visit represents an important advance in our field: nevertheless, it would be reasonable to anticipate that a center should want TLC data at the time that an RAS diagnosis is being made.

10. **Revising OPTN Bylaws Appendix L**

The American Society of Transplantation supports the proposal as written, and offers the following comments:

The proposed change in the interaction pathway between MPSC and OPTN member, when the member is under review, will allow for a more conducive exchange of information that may clarify the need for action or not against the member. This allows the member to have a voice before definitive adverse action is taken against the member program. The proposed policy describes how process efficiency, member rights, and bi-directional communication between the MPSC and the member would be improved with implementation of this proposal. We appreciate that the proposal was
developed not only by the MPSC, but that feedback was also solicited from members who had recently participated in program performance improvement reviews.

11. **White Paper on Manipulating Waitlist Priority**
The American Society of Transplantation is supportive of this proposal.

This white paper proposal outlines some of the guiding ethical principles of transplantation, namely beneficence and non-malefice, and acknowledges an identified problem of waitlist manipulation practices that are perceived by the public to benefit transplant programs over the patients they are intended to serve as well as unfairly benefiting one wait list patient over others.

The next logical step in the process will be to determine whether we have the ability on an organ specific level, to improve the system’s ability to identify such practices and to develop safeguards within the system to prevent them effectively.

The AST supports this proposal on the premise that transparency in waitlist practices will help to distinguish current standard of care practices from innovative methods that get patients safely transplanted sooner, from hasty ill-conceived futile care that may disadvantage a more suitable recipient.

12. **Guidance for ABO Subtyping of Blood Type A and AB Organ Donors**
The American Society of Transplantation is supportive of this proposal, and offers the following comments:

Related to the requested feedback from the Operations and Safety Committee regarding the section of the proposed guidance document that covers special considerations in subtyping including neonates and history of red blood cell transfusion, there are times when ABO sub-typing is not considered accurate enough and should be avoided. These include after a blood transfusion is given to a particular donor and in neonates. The guidance is sufficient in this regard and provides an appropriate amount of information. It may be helpful, though, to spell out what should NOT be done, based on specific circumstances and label the section of the text as something similar to, "Do not perform ABO sub-typing in the following conditions..." Sufficient detail and policy are not present, and we recommend greater clarify about what NOT to do rather than merely suggesting that one should consult a blood banking specialist in those circumstances, because then you open the door for heterogeneous recommendations.

The pediatric transplant community has particular interest regarding ABO guidance in determining subtyping methods for neonates. There is not consensus regarding testing timelines, interpretation of test results, or clinical decision algorithms.

This guidance document highlights several important points. From a safety perspective; two separately drawn pre-transfusion specimens must be used and must be in agreement with each other in order to assign subtype. From the terminology perspective; typing “non-A1” is more accurate than just assuming the subtype must be A2 if there is no reaction with the A1 lectin, since several other (rarer) subtypes are possible.
Why is the OPTN subtyping nomenclature different for A (A, non-A1) vs AB (AB- non-A1B)? We offer that either a comma or a dash should be used to separate the primary type from the subtype. Using a comma for A subtyping and a dash for AB subtyping is inconsistent. Instead, using a comma for both would reflect Tables 2-1 and 14-10 in OPTN policies 2.6.B and 14.5.B, respectively.

13. **Concept Paper on Improving the OPTN/UNOS Committee Structure**

The American Society of Transplantation opposes the concept paper as presented, and offers the following feedback.

We appreciate the concern that the current OPTN/UNOS organizational structure may limit opportunity for broader transplant community participation and may provide obstacles to incorporating minority and diverse perspectives on committees. We applaud the efforts by OPTN/UNOS leadership to, carefully and with introspection, examine how the current volunteer workforce reflects patients and professionals served by the OPTN/UNOS. As a Society, we are obligated to provide feedback to the OPTN/UNOS that accurately reflects concerns with this concept proposal that have been voiced by our constituencies.

**General Concerns**

1. **Is there evidence to support there is a problem?**

   The first step in the development of a proposal is to identify evidence to support a problem. The concept paper provides substantial support for lack of minority representation (African American and Latino) and diversity of perspective (recipient, donor family, living donor, etc.) on the committees. On the other hand, the support for a lack of opportunities to participate is a UNOS member survey. The document states that a consistent request from members is for greater participation in the policy development process. To strengthen the idea that there is a lack of opportunities for participation and identify areas for improvement, it would be of value to insert data and figures from the said survey. In summary, we need to more clearly identify the problem, as the solution proposed will have significant ramifications within the transplant community. Additionally, conversion to an Expert Council removes the ability of volunteers to directly participate in the policy development process for the less well represented constituencies.

2. **What will be the impact of the lack of regional representation on the proposed Expert Councils?**

   Contrary to the premise of the concept document, we believe the breadth of committees able to initiate policy is a strength, not weakness, of the current structure, and we believe regional representation on committees is essential to represent the very diverse centers across the US, and to coordinate committee work with regional meetings. A perfect example of how the current committee
system works well is the Pediatric Committee. At the Committee level, expert volunteers from around the country, representing all organs, identify concerns related to transplantation of children or concerns related to this vulnerable population with regard to existing and new policy proposals. The Pediatric Committee members then are able to fan out across the country, to share at the regional meetings the collective pediatric viewpoint. Without continued regional representation for children, the pediatric voice at the regional level may or may not be heard. The current committee structure for pediatrics ensures that the pediatric concerns related to existing or new policy proposals are brought to the regional meetings that are overwhelmingly attended by surgeons and physicians who care for adult patients.

3. Will the proposed change in committee structure result in increased diversity of perspectives on committees?

Contrary to its stated intent, we are concerned that this proposal will lead to decreased diversity of voices. The remaining committees are almost certain to be physician-dominated, further weakening the already decidedly weaker voices of patients, nurses, administrators, and others in policy-making. This runs counter to the intent of the Final Rule and to the stated intent to increase diversity.

Additionally, with the proposal for the new Expert Councils the entire leadership structure would be appointed by the OPTN president. With the current structure, regional representation has allowed for significant input from the regional councilors, and committees rich with patients, nurses, and others formalizes a voice for those professionals.

DTAC Related Concerns

We are particularly concerned with the dissolution of the Ad Hoc Disease Advisory Committee (DTAC) and being absorbed by the Operations Committee. DTAC considers issues related to transmission of disease through organ transplantation. The Committee examines individual potential disease transmission cases reported to the OPTN to confirm transmissions where possible. It reviews aggregate data on all reported cases to assess the risk of donor disease transmission in organ transplantation in the U.S. with the goal of providing (1) education and guidance to the transplant community toward preventing future disease transmission and (2) input in developing policy to improve the safety of organ donation through the reduction of donor derived transmission events. It may identify disease-transmission related patient safety issues to be addressed, as appropriate, by the OPTN. Historically, DTAC was part of the Safety and Operations committee. The increase in the number of reported cases and need to individually review them by transplant professionals with expertise in deceased and living donor evaluations and identification of potential disease transmission led to the formation of DTAC. As currently proposed by the concept paper, the Operations Committee will not have the appropriate composition of members to achieve its overarching goal and absorb the tasks that DTAC currently performs.

As currently composed DTAC has broad representation and its members currently include representation from adult and pediatric transplant infectious diseases,
hepatology, transplant pulmonology, transplant surgery, transplant pathology, transplant coordinators, histocompatibility laboratories, organ procurement organizations, CDC and HRSA. At the same time, any proposals that would provide further opportunities for participation, ensure minority and diversity in perspectives, as well as provide strong connections with the UNOS Board of Directors is of vital importance to the function of the committee. DTAC could benefit from including recipient, living donor and deceased donor representatives.

A secondary request is for the proposal to be more specific on how the Expert Councils will operate to ensure participation of the public. Without engaging the public, the proposed new criteria might not achieve the desired outcome.

Infectious complications may be the leading cause of death after transplantation, and disease transmission carries a significant risk of morbidity and mortality. DTAC reviews individual cases of potential disease transmission and provides guidance to the transplant community towards preventing future disease transmission and provides input into developing policies to improve the safety of organ donation through the reduction of donor derived transmission events. We are concerned about the impact that the proposed changes will have on all these important activities the DTAC performs. Further details on the new committee structures are needed to provide specific feedback on this issue. As currently outlined, the American Society of Transplantation Infectious Diseases Community of Practice foresees that our voice will potentially weakened as DTAC will be dissolved. Each year we propose candidates for DTAC membership, and if elected they represent the voice of our community of practice.

**Pediatric Committee Concerns**

The Final Rule, National Organ Transplant Act of 1984, and the Children’s Health Act of 2000, in aggregate, mandate that policies and procedures be developed that protect access to and insure the greatest potential for quality outcomes in vulnerable populations like children with conditions treatable by organ transplantation. Although we appreciate UNOS leadership approaching this potential topic in the form of requesting feedback on a “concept document”, the AST pediatric constituency opposes the concept of reclassifying the Pediatric Committee as an “Expert Council.” We strongly emphasize our belief that this proposal directly undermines the principles set forth in these guidance documents and the mission of the pediatric transplant community. As such, we do not support the concept paper in its present form and wish to propose alternative solutions to achieve the UNOS 2018-2021 Strategic Goals.

In the present UNOS Committee policy structure, pediatric-specific policy originates in one of three ways:

1. The Pediatric Committee organically synthesizes a proposal identified from discussion of a present practice issue or identification by evidence-based scientific research.

2. The UNOS Board directs the Committee to develop a solution to address gaps in present policies.
3. Other organ-specific Committees consult the Pediatric Committee for areas of overlap where policy formation may have unintended consequences on pediatric patients.

The pediatric constituency of AST strongly recommends a 2-pronged solution to address the widening gap between the standard of pediatric transplant practice and policy formation by:

1. Amending the 2018-2021 Strategic goals to include a pediatric-specific goal and an appropriate budgetary commitment, (See AST Response to UNOS Proposal 15) and
2. Developing an accompanying Pediatric Committee structure that will execute this new strategic goal.

We suggest that the Pediatric Committee remain in its present form with a Chair, Co-chair and Regional representation, At-Large Surgical representation (if not elected from the regions), At-Large Organ specific representative (if not elected from the regions), patient/donor representative, as well as elected pediatric professional representatives from the major pediatric organ-specific societies and associations (SPLIT, ASPN, AST Pediatric COP, and the IPTA). These organizations inherently possess oversight councils as well as internal communication networks to identify specific issues within the pediatric community that can be vetted for potential policy projects, but also can serve as a more transparent pool of subject matter experts if review and feedback on a particular topic, especially those which are organ specific, is required.

Secondly, we propose that the Pediatric Committee leverage in-person and virtual meetings outside of the present traditional semi-annual UNOS meeting structure to improve the efficiency and quality of discussion and subsequently make the policy formation process more cost-efficient and effectual.

This proposal places shared responsibility and accountability on OPTN/UNOS and the pediatric transplant community to co-develop innovative policies that serve the OPTN/UNOS Strategic Plan and goals, are compliant with the foundational guidance documents, and advance the mission of the pediatric transplant community.

Transplant Administrator Concerns

We would ask that the Transplant Administrators Committee not be placed in the Expert Council category. The lack of required administrator participation on the Board of Directors and other committees already leaves this important voice limited. This group has a wealth of regulatory and process expertise that is important in the overall policy development process. Eliminating the committee would constrain administrators to trying to get onto already crowded committees to have a policy voice.

Summary

In summary, while the AST is supportive of efforts to broaden transplant community participation and increase minority representation and diversity of perspectives, we feel the current proposal is at risk of not achieving those stated goals. We specifically are
concerned for the potential negative impact that the loss of regional representation and the loss of the ability to *directly* impact policy will have for constituencies that are converted to Expert Councils. For the reasons stated previously, we oppose the elimination of DTAC with absorption into the Operations Committee. Similarly, for the reasons stated above, we oppose the conversion of the Pediatric Committee to an Expert Council.

14. **Guidance on Requested Deceased Donor Information**

The American Society of Transplantation is supportive of this proposal, and offers the following comments:

The guidance document itself is very clear regarding which scenarios in which additional information should be gathered. The guidance document should be easily accessible by OPOs and transplant centers. Ideally, a reference to the guidance document would be included in Policy 2.11 which would direct OPOs and transplant centers to the location of this guidance efficiently.

The document, as it refers to kidney biopsies, could be strengthened by adding for inclusion the biopsy report where one is available. Additionally, pre-implantation biopsy reports would ideally follow the recommendations of a recent consensus paper (Liapis et al, AJT 2017, vol 17: 140-150).

The guidance document could be strengthened by including a specified time frame for review and updating of the document.

15. **OPTN/UNOS Strategic Plan**

The American Society of Transplantation supports the proposal and offers the following comments and questions for consideration:

For Goal 1: The statement on new initiatives pursuing policies and system tools for more dynamic donor/recipient matching may need to be further clarified in terms of specific policies being implemented across all organs. Will the focus be on better data management and analysis of OPO and transplant center performance after the key metrics are met in 2020?

For Goal 2: The definition of a vulnerable population is unclear

For Goal 3 or as a standalone Goal 6: The AST is aware of and has concerns relating to pediatric transplant candidate waitlist mortality. In 2016, 27 children on the kidney waitlist, 34 children on the liver waitlist, 60 children on the heart waitlist and 4 children on the lung waitlist, died prior to receiving an organ.

As such and in keeping with the goals elaborated on in the 2014 UNOS Ethics committee white paper on pediatric organ allocation, which specifically cites that pediatric patients in need of transplantation should always remain a top priority of strategic direction, resource allocation and policy formation, there is support from AST
for either adding a 6th goal specifically to address eradicating pediatric waitlist mortality nationally or incorporating under Goal 3 a specific initiative to eradicate pediatric waitlist mortality. The proposed budget for this initiative should prioritize supporting innovative ideas, data acquisition and analysis, as well as deployment of support staff to facilitate the critical communication between OPTN/UNOS leadership, and stakeholder transplant professionals to actualize this very achievable objective. This initiative would be in keeping with the original language and spirit of NOTA, the Final Rule and The Children’s Health Act (2000) and by specifically naming this as a 6th strategic goal, forward-thinking projects will be generated from the pediatric transplant community. Ultimately, this initiative, while bold, will stimulate innovation in patient advocacy and policy development that will result in the most-in-need children being transplanted at the most beneficial time with the best suitable organ allowing for the greatest potential for enduring transplant survival and transition to quality adult life.

While we recognize that incorporation of a goal to eradicate pediatric waitlist mortality could be accomplished within the current OPTN/UNOS Goals (specifically under Goal 3), there is precedent for this focus to be a stand-alone goal. In 2006, the annual goal set by the then President of UNOS, Sue McDiarmid MD, was to “eliminate pediatric waitlist mortality”.