The American Society of Transplantation responded to fifteen public comment proposals released for comment on August 3, 2021. The responses below were entered on the OPTN website.

Of note, this group of responses included the patient voice perspective, as discussed and submitted by the Society's Transplant Community Advisory Council. At the time of submission, this recipient-led group included six organ recipients, who received a presentation from UNOS representatives on the proposal before preparing their comment.

1. Require Lower Respiratory SARS CoV2 Testing for Lung Donors

The American Society of Transplantation strongly supports this proposal. This is a necessary and reproducible safeguard against potential transmission of a known donor-derived SARS-CoV-2 infection.

The implementation of a nucleic acid amplification test (NAAT) to specifically identify the RNA sequences that comprise the genetic material of the SARS-CoV-2 (COVID-19) virus on lower respiratory specimens for all lungs donors prior to transplant is appropriate and consistent with the UNOS policy to prioritize the recipients' safety by avoiding COVID-19 transmission to lung recipients.

NAAT testing result should be used in combination with clinical history and examination, radiographic findings (i.e.: CT Chest), other labs and BAL results in the assessment of lungs prior to acceptance.

Safely optimizing the number of transplantable organs under the pandemic is the highest priority. It is important to keep abreast of all available updates in diagnostics regarding the scientific advancements to carry out this aim. Use of lower respiratory COVID 19 NAAT testing from within or below the trachea is more likely to provide lung transplant clinicians with information needed to make the best decision in accepting or declining lungs for transplantation.

We offer the following comments for the DTAC's consideration:

- No timeframe for collection is included in the current proposal. We believe that timing should be made explicit and suggest that the relevant specimen be obtained, and proposed testing be conducted within 72 hours of organ recovery. This is in line with recommendations previously offered by the DTAC in other COVID-19 resources. We support this timeline to capture transmissible infections and to better assess risk to lung recipients and individuals coming in close contact.

- We suggest adding policy language so that once the COVD-19 public health emergency is resolved the DTAC conducts regular review of this testing requirement to confirm that it remains appropriate to continue.

2. Update Data Collection to Align with USPHS Guideline 2020

The American Society of Transplantation supports this proposal as written and offers the following comments for consideration:

Members supported the standardization of DonorNet data collection methods, as this is currently a barrier for current and any future data analyses. There was also support for collecting granular

data in non-text data submission fields, as this can assist transplant hospitals in identifying the specific risks for an organ more efficiently. (eg: https://pubmed.ncbi.nlm.nih.gov/33690910/)

3. Guidance for Data Collection Regarding Classification of Citizenship Status

The American Society of Transplantation is supportive of this proposal in concept and offers the following comments for consideration by the sponsoring committee:

The AST believes transparency and clarity in reporting information and a clear picture of the population we serve is valuable. However, we share concerns regarding the politicization of this topic related to the recent census process and results. We acknowledge that candidates may be reluctant to provide this information. Since most transplant programs need proof of financial support, care plan, and other objective data, it was felt that citizenship was a natural data element that should be collected considering the national resource of organs. However, we believe messaging is critical to clearly explain that these data will be used to assess equity in access to transplant healthcare, and not be used to determine transplant decisions, suitability, OPO or transplant program metrics, or resource allocation. Additionally, reassurance regarding the security of the data is important for both transplant professionals as well as patients.

We also believe it is important to clearly state the “why” up front, as these are not new data collection, but rather focus on how to most accurately complete the patient demographic fields. Additionally, we believe there is merit in sharing how the data has been used to date, including tying it to strategic goals of addressing disparities in transplant access and care.

Further, we believe it is critical that clarification be offered regarding the definition of a United States citizen. We believe that this is currently incomplete. For example, citizenship of pediatric candidates by virtue of adoption or a parent being a U.S. citizen is not currently included.

We strongly suggest that guidance be given related to the expected process in order to standardize this process operationally so that transplant programs know what is expected to answer the citizenship question without seeking to verify an individual’s legal immigration status in the U.S.

Finally, we understand the goal of this effort is to understand transplant tourism. To that end, we suggest that more clarity is needed regarding how this applies to deceased donation. Requesting citizenship status or date of entry could create barriers to deceased donation.

4. Ethical Considerations of Continuous Distribution in Organ Allocation

The American Society of Transplantation is supportive of this proposal in concept. Society members reviewed the concepts contained within the public comment document, including all potential ethical principles and the potential impact of a continuous distribution in U.S. organ transplant allocation. Overall, there was general consensus that the principles outlined in the document were well presented and supported by the OPTN. There was also appreciation for the depth in which the OPTN delved into the ethical principles of continuous distribution, and that the ideas presented were of sound logic.

The following comments are offered for consideration as the proposal continues to be developed.

<u>Flexibility and Adaptability</u>

Of note, a concern was raised regarding the flexibility and adaptability of a continuous distribution system within the current OPTN review structure. Specifically, if there were changes that needed to be made (e.g. weighting of certain factors), it was not clear the process through which these changes would be made. Would the OPTN require such changes to be routed through the biannual public comment cycle, or would there be another mechanism through which the transplant community could provide feedback on proposed changes? The Workgroup requests that the OPTN clarify this process of changing a continuous distribution allocation system moving forward in order to allow for appropriate community input.

Unintended Consequences for Patient Populations
Concerns were raised regarding potential issues of justice and equity affecting vulnerable groups (racial and ethnic minorities or children who are a minority in transplant) are not sufficiently considered in the white paper in its current form. We propose that existing literature describing the impact of various healthcare AI systems on equity indicators should be reviewed and cited in the white paper.

5. Update on OPTN Regional Review Board Project

The American Society of Transplantation appreciates the OPTN's effort to ensure sufficient and effective representation across regions-regardless of where the boundaries are drawn- and disciplines. The purpose of the OPTN Regional Review project is seeking to optimize OPTN governance and operational effectiveness by evaluating the role of regions. Regions were historically created from groupings of Donation Service Areas (DSAs) to help manage the national organ transplant network. These regional boundaries were based on patient referral and organ sharing patterns that were created in 1986. Accordingly, while this is not a concrete proposal, we are supportive of the concept of restructuring UNOS regions with the aims of improving representation and engagement. We acknowledge the diversity of the regions and recognize that merit in similar member-type groups working well for some activities, including the review of policy proposals and sharing best practices.

The following thoughts and feedback were offered as our communities of practice considered this update:

General Governance Feedback
Reducing the size of the OPTN Board of Directors and using other mechanisms such as advisory forums to provide input to a smaller Board from regional and special interest cohorts may allow the Board to be more effective and nimble in its actions.

We suggest caution in replacing the current POC structure with the proposed outline.

From the Transplant Administrator Perspective
We support efforts that seek to better serve the transplant and donation community, as well as our patients. A hybrid model may be able to be constructed to achieve the equally important goals of allocation equity, community engagement and active participation in policy development.
We additionally would support solutions that would be fiscally responsible, efficient and easily operationalized. We would not support costly solutions that would be difficult to implement or navigate.

From a Kidney Perspective

Regions have heterogenous groups with differing voices and usually doesn't lead to effective discussions. Large centers and OPTN power figures dictate the outcome of the discussion. There is a need to redraw the current regions as the new concentric circle distribution model of kidney and pancreas transplants has diminished the significance of regions.

With all of the three models, regional representatives will be “board members”.

> Model 1- No more regions but communities. It will create groups that will work in their own bubbles. This will help provide voice to smaller programs but the chance to learn and meet colleagues from larger centers will be taken away.
>
> Model 2- redrawn Boundaries based on new allocation system and national policy debates. This will take away the sentiments from regions. National meetings will be larger and it will be difficult to have input of smaller programs.
>
> Model 3 is a hybrid model with current regional structure but will have communities of interest. with Outline the pros and cons of 3 proposed models that will replace the regions in terms of four functions- representation, communication and feedback, operations, and data analysis.

Report generating/data analysis - will be possible only if some sort of regions is maintained (model 2 and 3). However, model 1 can include communities of practices of redrawn regions.

Representation seems best with model 1, as this model (Model 1) allows members with a common interest to come together, have more effective group discussions which will provide clarity to OPTN when debating on policy matters. For this reason, communication and feedback are best with model 1

From a Living Donor Perspective
What is the optimal governance structure to best perform OPTN functions?

Based on the information available in the Update document, the LDCOP EC opined that the hybrid model may be favorable, based on considerations including:

Ease of implementation by maintaining geographical relationships that are important when considering regional differences

Elevating the voices of patient and donor family stakeholders that would be grouped into national cohorts.

We ask for clarification regarding whether policy discussions would occur at the national or regional levels.

How should the OPTN organize members into smaller forums?

One suggestion is to create forums of all stakeholders around clusters of transplant centers within 250nm of each other given current allocation, to group the voice of stakeholders most likely to interact with one another in practice.

How should the OPTN ensure members have a voice in policy?

We suggest a model where all stakeholders votes are counted at a smaller level (e.g. 'regional') and are then transmitted to the board by representatives of the various stakeholders.

We would request a clear definition of 'advisors to board' given the reduced level of representation and size of the board.

What role should geography play in the OPTN structure and functions?

Geography often dictates waiting time for transplant, wait list practices, etc. Stakeholders who are proximate geographically will share interests and should have a voice to express geographic concerns in policy discussions.

From the Thoracic Perspective

We support the review of models for a new OPTN structure particularly with in the setting of the ongoing institution of continuous distribution models. There is little detail provided in the proposed structural changes so it is difficult to offer detailed comments and thus we do not endorse a particular model at this time.

Comments on specific suggested models:

Model 1:

Population density, transplant access, and organ availability are quite variable throughout the country.

As geographic factors are de-emphasized in continuous distribution models, separation into "alike communities" may improve national focus on equity and access. However, the ability to identify and respond to specific regional issues would be reduced.

Model 2:

Repurposed regions. The redrawing of regions based on population and OPTN membership has the potential to further increase disparities by overly empowering areas of greater population density/OPTN membership.

Model 3:

The hybrid model would seem to offer a potential to balance regional and national issues and resources. Of the three models, this seems to have the greatest potential for fair representation of interests and flexibility in the setting of ongoing changes in allocation and access but full details and renditions would be needed before we could endorse.

6. Report Primary Graft Dysfunction in Heart Transplant Recipients

The American Society of Transplantation strongly supports the proposal to collect data on Primary Graft Dysfunction (PGD). While additional time points for data collection would be desirable, we believe that there needs to be a fair balance between the amount of data collected and the additional administrative burden it imposes on transplant centers. Therefore, the collection of data

at two time points, 24h and 72h is reasonable. Long-term data already collected (morbidity, hospitalization and mortality), should be linked to the new data points. There was not unanimous agreement on this point, recognizing that hemodynamics are important in defining primary degrees of graft function and that this cannot be checked at another time interval. While the desire to streamline or minimize data collection to reduce the data burden on programs is admirable, it may come at the expense of greater granularity in understanding the outcomes of those patients who do not experience primary graft dysfunction.

The proposed data elements provide a reasonable framework. However, data acquisition should be streamlined such that, for example, if PGD is not present, then most of the other data element boxes should be automatically filled in as negative (eg device used, right or left PGD, EF). Since the intent is to collect hemodynamics on all patients, these would remain open for completion. This would prevent misclassification in cases where a temporary support device (I.e. IABP) may be left in position after transplant in the absence of PGD and would minimize the clicks for the person entering the data. If PGD is present, the next stem should define PGD-LV or PGD-RV in line with the ISHLT Consensus definition which is currently the only working definition. While most data may be reasonably obtained in the proposed timeframe defined after arrival in the ICU, initial EF may only be available from intra-operative TEE and second assessment may occur within a broader timeframe than 72h +/- 4h. We therefore propose that EF values are not strictly restricted to the 24h and 72h timepoints.

We believe that the starting timepoint for PGD should be in the OR as in rare cases severe PGD may lead to mortality prior to arrival in ICU or significant delay in arrival into ICU. The occurrence of PGD should be within 24h of transplant not within 24h of arrival in the ICU.

All vasoactive drugs should be named primarily by their generic nomenclature. Units for vasopressin should be unit/min. The ranges appear appropriate for adult and pediatric patients. Collecting vasopressor dosing in mcg/kg/mins with the option of also reporting in mcg/mins is reasonable.

The collection and entry of these data elements, while readily available in most EHR systems, will require additional resources, particularly for larger programs. Accordingly, we suggest clarification on the data collection to determine if there will be a potential increased burden of data entry.

With regard to consistency between programs, there may be a need to better define time points for entering vasoactive drug dosages – should they be captured at a single time point or should the highest dose within the +/- 4h time window be entered? This is particularly important as dosing and number of vasoactive drugs may change rapidly in the first 72h after transplant.

While this proposal does not suggest the PGD rates of centers will be made public, if PGD rates for centers are to be published, there should also be comparative analyses of factors which may contribute to it. Examples include, donor age, ischemic time, procurement distance, preservation method. This would allow a balanced assessment of programs willing to comply with broader sharing at risk of potentially increased PGD rates. We acknowledge that the use of the data is outside the scope of the proposal to collect the data but recognize that future utilization of the information should be carefully vetted.

We also ask that pediatrics be taken into consideration in this reporting as the indications for pediatric heart transplant are not the same as in adults and outcomes will be different. This will

require clear definitions (including pediatrics) and timeframes to ensure consistent, meaningful data is collected.

7. Amend Status Extension Requirements in Adult Heart Allocation Policy

The American Society of Transplantation supports this proposal in concept. We acknowledge that as proposed, this policy is designed to ensure that candidates at the highest status remain qualified beyond the initial period of time. For candidates who cannot be treated with other means, such as durable ventricular assist devices, the additional detail on justification forms will be straightforward to enter. The changes to the MCSD with thrombosis policy are also welcome. Increasing the length of time of extensions but requiring hospitalization will reduce paperwork while maintaining equivalent medical urgency.

8. Update Human Leukocyte Antigen Equivalency Tables

The American Society of Transplantation supports this proposal as written. Updating antigens in the tables is important from a patient safety standpoint. Highly sensitized patients may develop antibodies against HLA-DPA1, and the typing of HLA-DPA1 will improve the safety and accuracy of virtual crossmatch results. In addition, most labs already perform HLA-DPA1 typing for deceased donors, so this change will not add a significant burden to HLA laboratories, OPOs or Transplant programs.

9. Update on Continuous Distribution of Kidneys and Pancreata

The American Society of Transplantation is generally supportive of this proposal.

We recognize that the sponsoring committees have an incredibly complex and arduous task to bring this all together and commend them for their thoughtful and deliberate approach.

We offer the following responses to specific questions posed by the sponsoring committees:

What other factors should be incorporated into the allocation of kidneys and pancreata within a continuous distribution framework? Do you agree with the Workgroup's recommended attributes? Are there additional attributes of the current system you would recommend? And what additional attributes would you recommend for consideration as part of a future application?

Some other attributes that were discussed and could be considered and given priority points are: patient compliance/adherence, financial factors, multiorgan transplant, and Age > 65 (give preference to elderly who have been disadvantaged previously).

Some groups of patients (e.g. patients with diabetes) may be disadvantaged as they may be perceived to have lowest expected survival, and therefore they may be assigned lowest allocation composite score. However, timely kidney transplant may be especially important for these patients as they suffer from high mortality risks on dialysis.

The Workgroup asks for community feedback on the shapes of rating scales for each attribute (ex. linear, non-linear, binary, etc.). Additionally, the Workgroup welcomes feedback on how each attribute should be weighted in the composite allocation score.

We believe that the simulation models should be developed based on different attributes (with varied scales and weights assigned) to see which models would provide the desired outcomes. These models should not only predict which groups would benefit but also which

groups are predicted to lose. As suggested in the ethics white paper, there needs to be a means of rapid, iterative lookbacks to see if the agreed-to model is achieving the desired outcomes and pulling the plug on models which aren't measuring up in reality. The examples of unintended consequences include, but are not limited to small centers losing out, increased cold ischemia time compromising graft outcomes, decreased access for minorities).

In addition, the attributes must be rated and weighed in the framework of what we want to achieve- which is to improve patient and graft survival, improve access for minorities, efficiency of system, reduce cost, and utility. In particular we note that measures of compliance or adherence should not be based on socioeconomic status as this could unfairly disadvantage the socially vulnerable. Accordingly, measured values for adherence should be well vetted and validated.

Are there other measures of the efficient management of organ placement that should be taken into account in a points-based framework?

The new system should not disadvantage patients listed at smaller transplant programs located in the rural/suburban parts of U.S. There is concern that smaller or rural centers could be disadvantaged within this type of organ allocation system. As such, we request further information on how the sponsoring committees plan to monitor and prevent these potential unintended consequences for patients listed at smaller, rural centers.

How much importance should be placed on waiting time in the continuous distribution framework? How does the community feel about the idea of waiting time inversion?

Waiting time should be important. We are supportive of inverted waiting time which may help to decrease discard rates of high KDPI organs

Which kidneys should pediatric patients receive priority points for? Which kidneys should pediatric patients not receive priority points for? And what are some alternatives to KDPI for directing organs to pediatric candidates?

Considerations related to pediatrics raise two important issues regarding the current approach to continuous distribution: 1) aspects of the current allocation policies which prioritize subsets of organs (i.e. low KDPI, pediatric, DCD) to specific categories of recipients are not well captured in the proposed approach and 2) situations where a model driving one of the components of the score is not applicable to a subset of candidates (I.e. EPTS for pediatric recipients in this instance) have the potential to disadvantage that subset if not carefully considered.

Specifically, this movement to a continuous distribution framework is meant to provide a more equitable approach to matching candidates and donors and to remove hard boundaries that prevent candidates from being prioritized higher on the match run. We wish to emphasize how important it is to account for children in this system. We do not have all of the answers but would suggest that children be placed into the model on a continuous distribution based on their age (younger with more priority and the oldest approaching adult priority). Another possibility would be to group children into categories (for example, 1-6 year-olds getting 3 points, 7-12 year-olds getting 2 points, 13-18 year-olds getting 1 point). The basis for this differential in points would be related to the adverse effects of ESRD on growth and development being more substantial in the younger patients and the life of the patient and the graft.

One major concern is that this proposal does not give much detail as to how children will be allocated kidneys based on KDPI and there are faults with the current system. Currently children are prioritized for kidneys with a KDPI < 35 but this eliminates many kidneys from young donors from being offered to children. The KDPI determination was based on outcomes of adult and pediatric kidney donors transplanted ONLY into adult recipients. There are a lack of data to help determine if younger donors with KDPI > 35 would benefit children the same as an older donor with a KDPI <35. Short of a complete redo of KDPI, the pediatric community would advocate for continued priority for children of kidneys with a KDPI < 35 AND a version of age matching with increased weighting going to pediatric donors with KDPI > 35 being offered to children. This would allow the transplant hospital to look at the offer from the peds donor and on an individual basis decide if the "match" was reasonable for the child. Any agreed upon CAS needs to be modeled thoroughly to determine pediatric specific outcomes within a new continuous distribution allocation framework prior to implementation.

EPTS is currently not applied for pediatric candidates and the PCOP strongly feels that there is a need to either 1) introduce consistency of using EPTS for all recipients, or 2) factor this into the pediatric priority points.

In addition, there is still a concern in the pediatric community about multiorgan transplants taking away good quality kidneys from small recipients. We caution the use of the word "sickest" and stress that the main goal be maximizing the benefit of the donor organs rather than protecting the "sickest" patient. The sickest patients often have the worst outcomes. With the continuously increasing numbers of multiorgan candidates this needs to be addressed.

Finally, specific to the phrase: "To be consistent with kidney allocation policy, the Workgroup favors including priority points for prior living donors in pancreas and kidney-pancreas continuous distribution as well." We believe that exploring expansion even beyond pancreata is valuable here; that consideration should be given to all living donors (regardless of organ donated) having priority for transplantation across all organ types. We see this priority access to pancreas for former living kidney donors as opening the door to this broader consideration.

Overall, we believe that prioritizing children bears close observation. We support the need for this to be revisited across other organs, as simply giving children higher priority isn't always the best use of these organs.

Should the initial implementation of kidney continuous distribution mirror current approach to longevity matching, by awarding points to EPTS Top 20 percent candidates for KDPI Top 20 percent kidneys? Or should a more sophisticated approach be considered?

We believe that current longevity matching is appropriate

We encourage the OPTN Kidney and Pancreas committees to think more broadly about these points in collaboration with the Ethics Committee and other organ specific groups.

10. Review of National Liver Review Board Diagnoses and Update to Alcohol-Associated Diagnoses

The American Society of Transplantation is broadly supportive of the proposal as written but offers the following comments for consideration.

We believe the proposal offers more clarity and would seem to benefit all patients impacted. A specific concern was raised based on the belief that there are not enough data to support the safety of HCC candidates receiving immunotherapy prior to liver transplant. After much discussion, there was agreement that, though this is an ongoing area of investigation, HCC patients within UNOS downstage criteria and effectively downstaged to within Milan criteria (regardless of modality) deserve the opportunity to receive exception points.

We recommend explicit monitoring of the outcomes of patients who receive HCC exceptions following immunotherapy for the adverse events of concern (e.g. severe graft rejections, tumor recurrence, or death).

11. Establish Continuous Distribution of Lungs

The American Society of Transplantation is supportive of this proposal and appreciate the thoughtful effort that went into its development. We urge the OPTN to continue to seek better ways to measure cost when referencing proximity. We believe that as currently proposed, cost and proximity vs distance are both essentially looking at distance. The weighting of these elements is virtually the same using current measurements for cost unless long distances are involved.

We offer the following feedback for consideration:

1. Equal balance of waiting list survival weight and post-transplant outcomes:
The options compared appear to be 2:1 and 1:1 weighting with reference to waiting list survival and post-transplant outcomes. Were other weightings explored?

Page 13 states that the post-transplant outcomes measure included outcomes predicted out to 5 years, rather than one year. However, the example provided (figure 8, page 17, shows modeling based on 2-year post-transplant survival. Figure 8 does show that the 1:1 weighting results in the best overall composite (1-year waiting list survival and 2-year post-transplant) outcome. This is based on the combined weighting of 40, 45, and 50% of the total CAS. Modeling for higher combined weighting is not shown and thus, it is hard to know why the 50% combined weighting was selected particularly as the composite outcome at this weighting does not appear to have reached a peak/inflection point.

- Based on the modeling provided it does appear that 1:1 weighting of waiting list survival and post-transplant outcomes is preferable to a 2:1.
- It is unclear how 2 versus 5-year post-transplant survival impacts the model as only 2-year post-transplant survival is shown
- Combined weighting of pre- and post- transplant is shown to a maximum of 50% of the total CAS. The impact of higher combined weighting should be explored/shown
- Methods for determining and reporting all variables used to compute LAS should be rigidly standardized. Currently there is potential for variability in reporting resting oxygen use and 6-minute walk distances. This is further confounded for centers at altitudes significantly above sea level.

2. Pediatric waitlist survival score

There are fewer pediatric patients that receive lung transplants compared to other organs, and we are happy that the pediatric patients are being given priority in allocation schemes. However, the proposal as written reverses recent changes to the lung allocation policy that prioritize pediatric donors going to pediatric candidates under the age of 12 (in addition to the challenges related to incorporation of a subset of the candidate population for which modeling doesn't exist for a score component, this issue also exposes the fact that this proposal eliminates the aspects of current policy where subsets of donors are prioritized differently). Specifically, page 20 suggests that candidates<12 years who are priority 1 will receive 1.9075/25 waiting list survival points and those who are priority 2 receive a waiting list survival score of 0.44. Thus, transplant urgency will have little impact on CAS for candidates under 12 and they will rely largely on other factors particularly the 20 points assigned to pediatric candidates. Candidates aged 12-18 will receive waitlist survival points based on LAS score in addition to 20 points assigned to pediatric candidates.

- Based on above comments there is concern that there will be significant differences in CAS for pediatric candidates under and over age 12. This will need to be monitored closely to ensure that children under 12 have adequate access to donor lungs. At a minimum we would like to see modeling that verifies that this proposal won't consistently put age 0-11 candidates behind adolescents as seems likely to occur because as written priority 1 candidates < 12 years of age will get only of 20.54 of 50 potential points for medical urgency and post-transplant outcomes combined.

3. Post-transplant survival score for pediatric recipients under age 12. This appears to reflect limitations of the available data and thus, the outcomes for this group will need to be evaluated on an ongoing basis.

4. Candidate biology scales. ABO, CPRA, and Height are given equal weighting. We wonder if there is any data to support this equal weighting vs potentially increasing the weight of CPRA considering the challenges of matching a highly sensitized candidate. We do recognize there is variability in CPRA determination and efforts should be made to reduce the variability with standardized definitions and levels.

5. Candidate access scales. Providing weighting to younger patients is in alignment with ethical principles but the binary nature of this weighting is not ethically or biologically tenable. For example, a patient who is 17.99 years old will receive 20 points but a patient who is 18 will receive 0. We question the cut-off of points at age 18 and query as to whether equitable principles would be better served if there was a phase-out of points over a period of years after age 18.

6. Multi-organ allocation
This component of the policy proposal is complicated by the fact that allocation policies for heart, kidney, and liver are in evolution.

- Heart-lung. The proposal (page 40) is to continue to offer hearts to high status heart candidates (appears to be defined as status 1 and 2 but not clearly stated) within 500 NM from the donor hospital. It appears that the main driving factor from the heart standpoint would be transplant urgency and imminence of death. Unfortunately, this may create a disadvantage for sicker heart-lung candidates but uncertain how to meld the two when lung will be in continuous allocation and hearts not for many years. For lower priority/lower CAS candidates, the use of a CAS cutoff is reasonable. The proposed threshold of

28 would include 89% of heart-lung candidate. A threshold of 24 would include 98.5% of candidates. Thus, a slightly lower threshold might be more inclusive.

- Lung-liver: Unlike heart-lung the proposed allocation model does not consider liver transplant urgency. Again, for sicker liver candidates and lung-liver candidates, it might be preferable to allocate based on transplant urgency to avoid bypassing recipients at high risk for dying, similar to that suggested for heart-lung above. For lower priority/lower CAS candidates the use of a CAS cutoff is reasonable. Given the likely small number of lung-liver candidates, the proposed threshold of 28 which would include 98% of candidates.

- Lung-kidney: Based on the small numbers of combined lung-kidney transplants and the fact that transplant urgency is less of a factor for kidney transplant candidates, the use of the proposed cut-off of 28 which would include essentially 100% of candidates is reasonable.

7. Impact on Small Centers

We do question the impact of these changes on small-volume centers. Although the SRTR modeling doesn't provide center level data, it might be appropriate to monitor outcomes in relation to transplant center volume to better understand the true overall impact of this proposed change.

8. Epidemiologic Changes that Lead to Irreversible Lung Failure

While the system takes into account acute lung injury as ARDS which would include new diseases such as severe COVID-19 lung disease with SARS-CoV-2 we want to point out that COVID 19 disease and some other new epidemics may have geographic differences within the United States. For example, acute lung injury hospitalization with e-cigarette use, or vaping varied substantially State by State (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#map-case). Likewise severe COVID-19 hospitalizations and deaths are not evenly distributed across the country. Accordingly, OPTN should consider the need for flexibility to account for future epidemics that may impact populations requiring lung transplantation and ensure that the continuous distribution does not adversely impact patients that have geographic concentrations.

12. Reassess Inclusion of Race in Estimated eGFR Equation

The American Society of Transplantation applauds this proposal for clarifying eGFR is not mandated in allocation. The community is recognizing that, though unintentional, the equations that include race have systematically disadvantaged Black patients over time. We do not support the use of a dichotomous race variable to label individuals, as these equations require non-scientific decision-making using multiple unsound assumptions that are not evidence-based.

The AST's Kidney and Pancreas Community of Practice (KPCOP) policy workgroup (with representation from several Living Donor Community of Practice (LDCOP) members) had earlier conducted a survey of adult kidney transplant centers in U.S including members of the KPCOP and LDCOP, from December 2020 to Feb 2021 to seek feedback on some of the very questions posed by The OPTN Minority Affairs and Kidney Transplantation Committees in this proposal. A manuscript outlining the survey results has been accepted for publication by CJASN and will be available soon. Please see below the responses to the items on which feedback has been requested based on our survey results:

1. Which method of estimating or measuring GFR is your transplant program currently using? Why?

Respondents represented 57% (124/218) of adult kidney transplant programs and the responding centers conducted 70% of recent kidney transplant volume. Most (93%) programs use serum creatinine based eGFR for listing candidates. Twenty-nine percent also used measured 24-hour creatinine clearance (CrCl) in some cases, while only 7% reported using measured GFR in transplant listing practice. We didn't collect the data on which of the eGFR equations the transplant programs had been using at the time of the survey.

2. How would using a race-neutral eGFR affect your program?

Race-neutral determination of GFR requires either the use of cystatin C based GFR calculators, measuring 24-hour urinary creatinine clearance or measuring GFR via exogenous filtration marker. Our survey indicates that some of these alternative tests are not universally available. Cystatin C testing was unavailable at 24% of the responding centers and another 11% were unsure. Similar availability patterns were reported for access to measured GFR (mGFR) using exogenous filtration markers such as iothalamate, urinary iohexol, or 99m Tc-DTPA. Availability of these tests varied, with 61.6% of respondents reporting that their institution has capabilities for measuring GFR, while 31.2% did not have access to measured GFR testing and 7.2% were unsure.

Around 15% of responding centers are using creatinine based GFR estimators but have stopped reporting GFR values for Blacks and non-Blacks separately. Around 37% plan to assign a single value to all individuals (assuming non-Black), 30% plan to report a range from computation with and without a race modifier, and 20% reported a planned transition to cystatin C-based equations. A majority (94%) of respondents indicated the continued use of current race-based equations for calculating eGFR is inappropriate, with desire for change grounded in concerns for promotion of health-care disparities by current equations and inaccuracies in reporting of race.

3. What implementation challenges could use of a race-neutral eGFR present for your transplant program?

At the time of the survey, 39% of represented centers did not plan to remove race from GFR calculators, 46% were planning and 15% of had already done so. Among institutions that have dropped or are planning to drop race, 37% plan to assign a single value to all individuals (assuming non-Black), 30% plan to report a range from computation with and without a race modifier, and 20% reported a planned transition to cystatin C-based equations. While only 15% of responding centers have dropped race from eGFR calculation, there is considerable variability in reporting and use for waitlisting. Such variability may further exacerbate disparities for listing based on a patient's choice of transplant center to seek care.

4. What resources could assist in facilitating a smooth transition for your program?

Half of respondents prefer to await additional research and consensus guidance from ASN/NKF Task Force before adopting changes.
One-third of the responding programs lacked or were unsure of availability of testing for cystatin C or measured GFR.

5. What potential consequences should be considered during this proposal's development?

Most respondents (71%) believed that elimination of race would allow more preemptive waitlisting for Black patients, but a similar number (69%) also raised concerns that such an approach could incur harms. Key reasons for believing current approaches to GFR estimation are not appropriate include concern for unjustifiably treating race as a biological category rather than as a social construct, concern for perpetuating or extending extant healthcare disparities, including among multi-racial individuals with some Black heritage. However, respondents also registered potential harms of dropping race from eGFR calculations, including overdiagnosis of CKD, premature dialysis initiation and diagnosis of allograft failure, and underestimation of kidney function in screening living donor candidates.

Both sides to the argument, keeping or eliminating the race coefficient in the CKD-EPI eGFR equation have some merit. No doubt there are several issues with using race in the eGFR equation, including reliance on 'race' as reported in the electronic medical records with no distinction of multiracial individuals. These reflect challenges to the application of the formula at an individual level.
However, we do know, as is noted in the proposal, that compare to White individuals, Black persons have a higher serum creatinine at the same measured GFR. The CKD-EPI cohort had good representation of Blacks at 31.5%, and recently published data shows that removal of the race coefficient introduces a median bias of -6.1 ml/min/1.73m^2 for Black candidates (Diao et al, NEJM 2021).

Removing the race coefficient will reduce one kind of disparity in nephrology, but if we actually start to underestimate eGFR for all Blacks, that will create/ increase CKD burden for several Black individuals and potentially create a preexisting condition with consequences for medical care, drug dosing and barriers in equitable access to health, disability, life and long-term care insurance. In the United States, OPTN policy mandates that living kidney donor programs perform timed creatinine clearance or measured GFR to assess donor kidney function. However, if a program uses eGFR to screen possible candidates, Black donors may be inappropriately excluded, which would aggravate disparities in living donor transplantation for Blacks. In summary, there is a need to reduce disparities in access to the kidney transplant waiting list. An alternative may be to encourage or require a cystatin C or other race neutral measure of renal function for transplant referral and for waitlisting.

We suggest the Minority Affairs Committee consider a policy that prohibits the use of race-based methods[1] rather than mandating a specific method or equation for eGFR.

[1] *Hoenig MP, Mann A, Pavlakis M. Removal of the Black Race coefficient from the estimated glomerular filtration equation improves transplant eligibility for Black patients at a single center. Clinical Transplantation. 2021; in publication*

13. Enhance Transplant Program Performance Monitoring System

The American Society of Transplantation is supportive of moving beyond the current one-year outcomes used to assess transplant programs but has considerable comment regarding this proposal as written. It is unclear whether this proposal will have a positive impact on access to transplantation or an increase in the total number of organ transplants. We do wish to note our support for the principles applied for creating an effective metric. We would be pleased to see the

OPTN continue to apply these principles in the development of future policy language related to transplant center and adapted to apply to OPO performance metrics as well. Additionally, we recognize the critical timing of this effort. The donation and transplantation community has the opportunity to leverage these changes to improve system-wide performance by aligning with OPO metrics and addressing the potential competition with CMS metrics for dialysis programs. We suggest that it may be wise to consider explicitly adding the alignment with performance metrics for other components of the system as an additional principle for creating an effective metric.

Although we are encouraged that there was emphasis that any one metric would not be a firm trigger, there was concern that the previous near two-decade experience where the lack of change of the O/E standards as the outcome SD became narrower and narrower resulted not just in stifling of innovation, but also decreased access to transplant, results in the group being somewhat apprehensive of hard cutoffs that don't explicitly say that they should be adjusted with time. It is further acknowledged that the modelling for outcomes, while often reasonable, makes compromises that may inappropriately impact multiple risk situations in a way that may discourage transplant (e.g. CAD as a yes/no risk factor when it is a continuum of disease, the lack of interaction between DCD status and donor age, the lack of WIT in DCD risk calculation, etc.). While such issues may average out with large numbers, center volumes (even for the largest centers) are such that local impact can be profound if such models are overly rigorously interpreted by regulatory bodies or payors. There is a concern that audits and site visits may be viewed as punitive by hospital administration who may be less versed in the statistical modeling utilized for transplant, resulting in inappropriate pressure to do "less risky" transplants; this could be counterproductive. For this reason, educational outreach to both transplant centers and hospital administration is encouraged. The AST believes that there is value in emphasizing the role of the MPSC as an educational tool that helps programs improve their practice in a non-punitive, evidence-based manner. We believe that a strong educational effort by the OPTN to highlight this message will help to combat the negative narrative here and aid centers in using flagging as a tool in educating administrative staff and seeking resources to strengthen programs.

There was significant concern that adding a pre-transplant mortality metric – which was meant to incentivize performing more transplants – may have the opposite effect of transplant centers not listing or activating high risk or difficult to transplant patients because their deaths or inability to be transplanted (which may be totally unrelated to organ acceptance patterns) will damage their wait list metrics. This problem could be particularly acute in areas of the country with short wait lists such that each wait list death would have a significant impact on their metrics. Less than 30% of end stage organ disease patients make it to the wait list and we are losing many more patients in the referral/evaluation step than after they make it to the wait list, and any policy changes that exacerbate barriers to care will worsen any inequities in access to transplantation. This caused quite a bit of concern for members of the Kidney and Pancreas Community of Practice, as kidney patients are most frequently managed by their local nephrologists and dialysis unit—unlike most other pre-transplant patients. It was acknowledged that the bar for this metric is set at a currently reasonable level but given that there is little that the transplant centers can actually do to impact this metric that may not either decrease access or game the algorithm, *for kidney*, this particular metric seems most prone to future misapplication, gamesmanship, and inappropriate loss of access to the waitlist for various groups of patients who may be considered higher risk for waitlist mortality. While we acknowledge the desire/need to find a metric for waitlist management, there

was concern that at least for kidneys where pre-transplant kidney patient care is at the level of the community nephrologist and not the transplant center, it would be useful to help develop standards of waitlist management. Absent agreement on standards of waitlist management, what is the standard of de-listing and waitlist evaluation? We believe that better surveillance and care of individuals on the waitlist is crucial and appropriate resources must be allocated to optimally manage these needs.

The second metric, offer acceptance rate ratio, was less controversial and was generally conceptually supported. There was concern that the approach of using any refusal as the same as a donor refusal would cause misapplication. For example, current refusal codes in the 810's, which are recipient specific, may have different implications that those in the 830's (donor specific). As an example, a kidney donor with significant AKI may not be a great match to a frail recipient with CHF, but the same center may happily use that same kidney for other candidate populations. That said, the fact that the new offer filter function in DonorNet exempts filtered patients from the calculation was considered supporting the intent of this metric in a way that made it much less controversial (while acknowledging that it may take a couple of years to reach a steady state of filter use).

The third and fourth metrics, 90-day and conditional 1-year graft survival were not considered controversial and were embraced, with the caveat that care must be taken to avoid overemphasis of a "narrowed bell curve," and that the actual cutoff should be adjusted over time. Similarly, with similar caveats, the separation of pediatric outcomes was not controversial.

The Society shares the following thoughts for the MPSC's consideration:

- 90-day graft and 1-year graft survival conditional on 90-day survival seems to be overlapping, and perhaps a longer term (2 or 3-year graft survival should be considered)
- Concerns were also raised about the risk adjustment being performed that weigh into evaluating organ acceptance offers and waitlist mortality. It was felt that not all relevant factors are accounted for, particularly in the case of patients with significant non-liver-related cardiopulmonary comorbidities whose actual risk may not be captured, but who still benefit from liver transplantation in experienced centers.
- Same concern regarding elevated risk of waitlist mortality/dropout was made for centers who are aggressive in listing extended oncologic indication patients for transplant (HCC beyond Milan criteria who may be even beyond UNOS DS criteria but who may benefit from LT, unresectable cholangiocarcinoma patients – both hilar and intrahepatic- who are not typically considered at most centers. These patients all come at a higher risk of waitlist dropout and mortality- but this needs to be accounted for in the risk adjustment.
- The development of ratios that are risk adjusted should incentivize the overall number of transplants and allow the identification of behaviors that can be adopted by other transplant centers to improve or modify the care provided to transplant patients. We suggest also that continuous monitoring and evaluation of the currently selected and new variables should be adopted to adjust the models in the future based on future observations.
- The number of VCA transplants performed at any one center and in the nation is small. It will be necessary to develop metrics that address the unique circumstances of VCA transplants and at the same time carry out the duty of the OPTN in assessing program outcomes which would include VCA transplants.

- One area of concern is the decision to adjust the thresholds in order to "flag" a comparable number of programs. We ask that the MPSC provide some evidence that the flagging process has actually improved outcomes and hasn't negatively impacted innovation in the field.

Of importance, this is the first proposal where the Society's transplant community representation shares its feedback. The AST values the patient voice in considering these changes. The thoughts below were submitted directly from the AST's Transplant Community Advisory Committee, currently comprised of transplant recipients.

The Transplant Community Advisory Council, a body of the American Society of Transplantation with membership comprised of organ transplant recipients, is generally supportive of this proposal and offers its thoughts from the perspective of the transplant patient for consideration.

While we applaud the effort to enhance standardized patient safety and transplant quality, we believe that more can be done to improve the monitoring system and raise awareness and transparency for the "customers" that it serves.

We remain very uncomfortable with the one-year outcome as a measure of success, and strongly believe that long-term outcomes be part of the discussion when assessing patient safety and quality of life. From the viewpoint of a recipient, we are grateful for every day of life we receive from a transplant, but we don't go through the physical and emotional challenges of the awaiting and receiving a transplant with a goal of just 365 more days of life. We strongly believe that this element should be addressed in this proposal. We understand that success will look different for every patient and may differ by organ type, but we support continual and intentional discussion to ascertain the appropriate metric.

We also recognize that this singular metric of one-year survival cannot be the focal point for transplant evaluation, as it impacts the center's decision-making process related to listing candidates, acceptance of organs, and perhaps even post-transplant care. Moreover, it appears that this metric sets a low bar that nearly all transplant centers are able to meet reliably, thereby creating consistently favorable metric-based data that is made available to the public. We'd like to see more work to encourage performance growth and positive change to challenge the status quo in transplant survival. Comfortable goals or metrics create stagnancy and do not encourage the innovation that will ultimately lead to longer life post-transplant and perhaps fewer returns to the waiting list. This, in turn, could increase the number of available organs so that more patients can receive the gift of life.

While we appreciate the specialty of transplantation and the concept of confidential medical peer review, we do share concerns regarding the closed process in general. We question whether this proposal, that may be a step forward for transplant professionals, is also a step forward for protecting and serving patients. While we trust and respect our individual providers, a better understanding of the transplant program around them would be valuable information. We do not believe that the SRTR data goes far enough to provide transplant patients with information that may be critical to their self-care, patient advocacy, and decision-making when cause for concern arises regarding the safety and fitness of particular transplant programs. Organ-refusal data, for instance, is one type of information that is of great importance to us as consumers within the transplant system.

We recognize that information gathered by the MPSC can be sensitive or complex and may not be of interest to every organ transplant or recipient. However, we believe strongly that transparency in the healthcare arena is vitally important and can be achieved while maintaining sensitivity to privacy/HIPPA considerations as well. It troubles us that we are able to glean more information about restaurant food safety grades given by inspections (they are posted on the door) than we are privy to regarding the transplant programs that treat us. While some patients may not have the means to select or change their transplant program based on their review of this data, we argue that they should at least be aware of any serious weaknesses that may exist in their care—if only to try to avoid the consequent pitfalls. Patients are a big part of the success of their transplant care, after all; a paternalistic approach to sharing information, then, is not appropriate or acceptable.

Overall, we appreciate the need for rigor, measurement, and accountability in this area and the attention being paid to this by the MPSC. However, as patients, we are not sure how these proposed changes will impact our individual care, treatment, and quality of life in a palpable, positive way. We believe that the MPSC should consider additional factors or metrics, including candidate and recipient quality and extension of life measurements that will improve the existing transplant monitoring system. We believe that the outcome of these changes will ultimately advance the field of organ transplantation, enhance patient safety, and increase the quality and longevity of post-transplant life. And, finally, we also firmly believe and wish to emphasize our view that increased transparency is critical for both patient safety and patient choice.

14. Data Collection to Evaluate Organ Logistics and Allocation

The American Society of Transplantation is generally supportive of this proposal. These data are already collected and should not be expected to increase data collection burden on transplant programs and OPOs.

Several comments were shared by the organ-specific communities of practice for consideration:

1. It should be clarified as to who has the responsibility to put in the final kidney pump numbers in the donor net- OPOs or transplant centers. A kidney that is initially on pump may be shipped on ice to the transplant center and vice versa. If a transplant center is receiving the kidney on pump, it could be the center's responsibility to upload those final values, otherwise, OPOs must provide those values.
2. There must be a clear delineation of the difference between the revised definitions and those that are pre-existing.
3. With the new allocation, increased use of organ transport by planes, increase in cold ischemia time, and possibly higher turn down of offers, the cost assessment is critical to maintain the efficiency of organ logistics and allocation. We are concerned that the cost was left out of the proposal.
4. The rationale for changing from 6-digit provider number to 4-digit OPTN center code and 3-digit center type of the transplant center team recovering the organ has not been explained. A transplant center accepting the organ might want to communicate with the recovering surgeon about the organ and it is not clear if the recovering surgeons' information would still be available.
5. Specifically, from a thoracic organ transplant perspective we agree with removing *"intended or"* from the "*Left/Right Lung machine perfusion intended or performed*." EVLP is now standard at many programs and the designation of "*intended*" is no longer of significant relevance.

6. We agree in concept with the modification of "*Kidney pump values*" to include time, flow, pressure and resistance.
7. Although we understand the rationale for leaving cost assessment out of the new proposal, we are less certain that existing data can give a clear picture of true cost. As the cost of transplantation is increasing significantly (and could limit the ability of small and medium sized programs to continue to support SOT), we feel that it ultimately would be worth the added complexity to consider the development of a more robust and specific cost assessment. Cost is extremely important for access and as the costs of donor acquisition rises, the coverage is not, which could force programs to start to limit access based on payers or limit donor acceptance to more local donors thus forcing patients longer wait times.
8. We agree that collecting further specific data on late turndowns is very important. We agree that the committee should remain engaged with DAC to ensure that this does happen in a meaningful timeframe.
9. We offer a recommendation to classify the perfusion type of every organ.
10. Data elements that specifically inform disparities and access to transplantation should also be considered.

In addition to these specific considerations, we feel that this situation may emphasize the value of utilizing focused, dedicated studies to answer questions rather than broad data collection changes. We suggest that this should be a future consideration when specific topics that will inform policy change are under consideration.

15. Establish Membership Requirements for Uterus Transplant Programs

The American Society of Transplantation is generally supportive of this proposal. We believe that it brings needed structure and defines the minimum areas of expertise required to conduct uterus transplantation.

A concern was raised regarding the definition of organs covered. Clearly, uterus, cervix and vagina, would cover the organs transplanted as part of a uterus transplant to accomplish the goal of carrying a fetus and delivering a live baby. A strong recommendation is that the definition be inclusive of all female genital organs. The rationale for this change is to avoid a program considering performing any form of female genital tissue transplantation that would not fall under this policy but that requires the similar infrastructure and expertise already covered by a uterus transplant program. We believe that the OPTN committee made great progress with defining the needed areas of expertise that would build a team that is able to care for female or transgender patients undergoing any form of genital tissue transplantation and it would be applicable to allow this policy to cover all female genital tissue (and another one for all male genital tissue in the list of body covered parts), so that any program that would offer any such transplant, would have in place an OPTN policy that would guarantee the safety of patients and donors without the need to formulate new policies with the delay in development and implementation given the needed timeline for policy creation. On the same lines, it would also avoid an "other GU" category.

Another concern was raised about the proposed required observations for the primary surgeon to complete at another institution to be approved to perform living donation. Some in the AST pointed out that this should not be necessary. The rationale is that that the expertise needed to perform a safe uterus procurement is most definitely obtained by performing hysterectomies with the added need to obtain long vascular pedicles, though we appreciate the important technical differences in hysterectomy versus recovery for transplantation here. A high-volume

gynecology practice with a reasonable number of hysterectomies may be more important with caveats on transplant training, noted below. A gynecology surgeon can observe a multi-organ deceased donor procurement to be acquainted to the donor procurement environment. We are concerned that observing transplants or procurements for transplants at another institution may become increasingly difficult as the numbers of uterus transplants are declining and the number of active programs is low. In addition, this could be an unreasonable financial burden once initial financial support from institutions ceases and it becomes a commercial practice, with no third-party payers currently supporting or offering uterus transplantation. This is unlikely to change with the limited national coverage for fertility therapy in general. Finally, the credentialing process and/or visitor process for a visiting surgeon vary per institution and it will add logistical challenges (e.g., at the hosting institution and/or leaving a clinical practice).

Unlike other solid organ transplantations where the transplant is most often lifesaving, the goal of a uterus transplant is to enable women or transgender individuals to grow a fetus in the transplanted organ, with the aim of a live birth. Accordingly, we would like to emphasize a few points that in our mind are critical for any uterus transplant program:

1. The primary surgeon or OBGYN should undergo training in immunology/ transplant medicine or be in collaboration with the local transplant team– to enable them to provide adequate counseling, appropriate immunosuppression coverage, and treatment of its side effects to enable a healthy pregnancy and good long-term outcomes for the mother.
2. The ethical principles of living donation programs of separation between the medical teams dealing with the donor and the recipient should be adopted, including a specific and separate living donor coordinator and advocate.
3. We believe it is important to clarify that the existing OPTN Bylaws outlining “Other Transplant Program Personnel” including Clinical Transplant Pharmacist apply to Uterus Transplant Program requirements, as this detail was not explicitly outlined/mentioned. Since all hospitals must have other solid organ transplant programs in order to establish a designated VCA transplant program, including uterus. As such, the support personnel requirements described in Appendix D of the OPTN Bylaws (including Clinical Transplant Pharmacist, Clinical Transplant Coordinator, Financial Coordinator, Mental Health and Social Support, and Medical Expert Support) should align with the membership requirements for Uterus Transplant Programs. This is important to ensure quality patient care, as these patients are on maintenance immunosuppressants like other transplant recipients and require close pharmacologic, multidisciplinary management.
4. The recipient team should include a social worker/psychologist who is expert in female and transgender reproductive issues and can provide the necessary support system to the donor. Especially as not all transplants end with a live birth. There should also be a discussion of alternatives to uterus transplant, i.e., adoption and surrogacy, once again as not all transplants end with a live birth.
5. This proposal mentions the psychological evaluation and requires centers to have clinical resources to perform a psychosocial evaluation of the living donor, makes comments to the effect of psychosocial evaluation of the candidate but no clear comment on evaluation of the candidate, which we believe may be very impactful as well.
6. Very minor wording clarification is needed: J5.B. Living Donor Psychological Evaluation – this should be changed to “Living Donor Psychosocial Evaluation. As currently written (i.e., Psychological), this would require all programs to have a clinical or counseling psychologist as there are state law requirements about who can conduct a “psychological evaluation.” Use

of the term “psychosocial” is much broader and includes psychologists, social workers, psychiatrists, etc., which I believe is the intention of the committee.