Introduction

The OPTN Executive Committee met in Richmond, Virginia on 06/26/2022 to discuss the following agenda items:

1. New Projects from the Policy Oversight Committee
2. OPTN Policy 1.3: Variances Project
3. Regional Review Project: Workgroups and Next Steps

The following is a summary of the Committee’s discussions.

1. New Projects from the Policy Oversight Committee

Dr. Nicole Turgeon, the Chair of the Policy Oversight Committee (POC), presented the new projects that the POC has reviewed and approved. The OPTN Kidney Transplantation and OPTN Minority Affairs Committees are jointly sponsoring a *Modify Candidate Waiting Times Affected by Race-Based eGFR Calculations* policy. The OPTN Liver and Intestine Transplantation Committee is sponsoring the *Review of Liver Variances in OPTN Policy*. The OPTN Ethics Committee is sponsoring the *Ethical Considerations of Normothermic Regional Perfusion* white paper. The Committee voted unanimously in support of approving the three projects as recommended by the POC.

Summary of discussion:

*Modify Candidate Waiting Times Affected by Race-Based eGFR Calculations*

The Chair emphasized the timeliness of this project and is supportive of the work being done to address this issue. A member inquired how the Committees intended to operationalize this policy to identify the race-adjusted qualifying creatinine. The Chair noted that POC approval is the early stage of project approval and the committees will have time to consider the process to operationalize the policy. A member also inquired how this policy would be different from any other instance where a patient had a qualifying eGFR calculation prior to listing, but did not have a qualifying eGFR at the time of transplant evaluation. A member noted that this proposal was an opportunity to rectify a disadvantage that Black/African American patients have endured and voiced their support for exploring similar pathways for other groups in the future.

*Review of Liver Variances in OPTN Policy*

A member clarified that a variance in policy creates a temporary policy to test a potential, future, national policy on a small scale to determine its success. A member shared that pediatric liver transplant programs underutilize the split liver policy variance and suggested that the review of the open split liver variance occur in collaboration with the OPTN Pediatrics Transplantation Committee. The presenter noted that this proposal is meant to align the end dates of the current variances with the implementation of the liver continuous distribution allocation framework. The presenter will share the sentiment about the Pediatric Committee’s inclusion but noted that the Vice Chair of the Pediatric
Committee was present when this proposal was approved and did not express any concerns. With this being said, the Pediatric Committee will be included in developing the liver continuous distribution framework.

A member inquired if there are additional variance policies that need revision. A member noted that these are all of the variances in liver policy and the purpose of this review will allow the end dates to be adjusted at once as opposed to in multiple different policy proposals. It was clarified that the Hope Act is the only additional variance currently in OPTN policy.

**Ethical Considerations of Normothermic Regional Perfusion**

The Chair added that the OPTN Presidents asked the Ethics Committee to take this project on. A member voiced their support and noted that there is a large joint society group working on this topic as well. A member inquired if white papers proceed through the same policy development process as other Committee projects. The presenter clarified that the process for review and approval is the same for policies and white papers. A member suggested including representatives from the OPTN Lung and Kidney Transplantation Committees.

2. **OPTN Policy 1.3: Variances Projects**

The Chair reviewed the background of policy variances and introduced the policy modification. This project would remove the word ‘amend’ from OPTN Policy 1.3 to clarify that the OPTN Board of Directors would not amend a policy at any time without feedback from the community. Variances to policies follow the same policy development process as all other policy proposals. The Committee voted unanimously to recommend this policy proposal to the OPTN Board of Directors for approval.

**Summary of discussion**

A member inquired how this issue was identified. The Chair responded that support staff are constantly reviewing OPTN policies to ensure that they reflect the intent and process that the community follows. A member clarified that this change is to ensure there is no misconception that substantive amendments to variances can occur without review and feedback from the community.

3. **Regional Review Project: Workgroups and Next Steps**

The Chair reviewed the progress that the Executive Committee and its workgroups made as a result of the Regional Review project. The Chair outlined the future actions to be taken, including reviewing the regional boundaries every three years with the next to begin in April 2025. The Committee reviewed the resolution they voted on during their April 25, 2022 meeting.

**Summary of discussion:**

A member praised the success of the Patient Engagement Workgroup. A member emphasized the importance of regularly partaking in this process to better understand how the regions meet the needs of the community as transplant continues to evolve. A member noted that the resolution is missing any inclusion of patients as necessary to collaborate. A member highlighted that although the regional boundaries did not change, there were significant upgrades to how the OPTN is governed and fosters patient engagement. A HRSA representative suggested developing a press release or other communications to share the accomplishments of the regional review project.

**Next steps:**

The Chair will present the final report on the Regional Review with the OPTN Board of Directors on June 27. The Regional Review update, final recommendations, and completed actions will be shared during summer 2022 regional meetings.
Attendance

- **Committee Members**
  - David Mulligan
  - Jerry McCauley
  - Lisa Stocks
  - Irene Kim
  - Mindy Dison
  - Brad Kornfeld
  - Matt Cooper
  - Patrick Healy
  - Richard Formica
  - Stacee Lerret
  - Valinda Jones
  - Brian Shepard (Ex Officio, Non-Voting)

- **HRSA Representatives**
  - Chris McLaughlin
  - Frank Holloman
  - Shannon Taitt

- **UNOS Staff**
  - Carson Yost
  - Delaney Niles
  - Lindsay Larkin
  - Laura Schmitt
  - Rebecca Murdock
  - Roger Brown
  - Susie Sprinson

- **Other Attendees**
  - Nicole Turgeon