OPTN Network Operations Oversight Committee
Meeting Summary
April 9, 2025
Webex

Andrew Kao, MD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 04/09/2025 to discuss the following agenda items:
1. Welcome
2. Revise Conditions for Access to the OPTN Computer System, Implementation Update
3. OPO Relationships with Research Organizations
4. Member Security Attestation Update
5. Closed Session
6. Adjourn

The following is a summary of the committee's discussions.

1. Welcome

Andrew Kao, Chair of the Network Operations Oversight Committee (NOOC), welcomed committee members and advisors to the meeting and presented the agenda.

2. Revise Conditions for Access to the OPTN Computer System, Implementation Update

Dr. Kao provided a detailed overview and update on the implementation of the revised conditions for access to the OPTN computer system. He reiterated that this policy had been formally approved by the OPTN Board of Directors during its December 2024 meeting, marking a significant shift in how member organizations interact with and access the secure system infrastructure supporting organ transplantation operations.

Summary of Discussion:

Contractor staff reviewed the rationale behind the policy changes, noting that they were developed in response to increasing demands for system integrity, enhanced data security, and stronger accountability measures across all member institutions. He emphasized that the revised conditions were not only necessary from a compliance perspective but also reflected the broader organizational commitment to safeguarding sensitive health data and ensuring that access to OPTN systems is appropriately controlled and monitored.

Key milestones in the policy's development, including stakeholder engagement during the drafting phase, formal board approval, and the commencement of implementation activities were also highlighted during the discussion. Additionally, an overview of the current implementation status was provided, emphasizing that system access forms and attestation procedures had already begun rolling out to members. It was also noted that training materials and support documentation had been disseminated to ensure that members understood their responsibilities under the new requirements.

There was a clarification of expectations presented for member organizations, including timelines for completion of access verification and attestation, procedures for addressing noncompliance, and methods for submitting required documentation. It was pointed out that while the implementation phase was progressing on schedule, continued collaboration and responsiveness from the member community would be critical in meeting the full compliance deadline.

Next Steps:

The OPTN Board will follow up with NOOC leadership to make more appropriate policy language related to those "permissible, time sensitive" research that can be done with direct access to the OPTN computer system verses what research should continue to go through the standard data request process.

3. OPO Relationships with Research Organizations

Lori Markham, Vice Chair of the OPTN Organ Procurement Organization (OPO) Committee, lead the second agenda item discussion concerning OPO relationships with research organizations. A number of key considerations surrounding these partnerships were addressed including ethical standards, data governance, and transparency in operational practices.

Summary of Discussion:

Ms. Markham began by explaining the increasing intersection between OPOs and research entities, specifically in the context of advancing medical science and improving transplantation outcomes. She acknowledged that while such collaborations can offer significant value, they must be governed by ethical standards that prioritize patient welfare, respect for donors and families, and responsible data stewardship. It was underlined how these partnerships often involve the sharing of medical data, imaging, and other clinical information, and emphasized that this information exchange must occur within a secure, compliant, and well-documented environment.

A key element of the discussion centered around transparency. It was stressed that OPOs must be fully transparent not only with their internal stakeholders but also with the public, particularly when it comes to how donor organs or associated data are used in research settings. References were made to existing policies that guide this work, and attention was called to the importance of establishing formal agreements with research institutions, including defined scopes of access, limitations on data use, and documentation of consent when applicable.

Operational practices were also addressed, including how access to clinical systems is currently granted to researchers, the types of read-only permissions often provided, and how some OPOs have implemented tiered access based on user roles. She invited committee members to share their experiences and challenges in this area, recognizing that operational models vary across organizations. Several participants responded with examples of how their respective OPOs handle research access, noting efforts to streamline processes while maintaining control over data integrity and compliance.

Next Steps:

No decisions made, discussion only.

4. Member Security Attestation Update

Summary of Discussion:

Bryan Carnahan, Governance, Risk, and Compliance Manager, provided an update on the Member Security Attestation process. Bryan spoke to the purpose of the security attestation requirement, explaining that it serves as a critical measure to strengthen cybersecurity practices across all OPTN

member organizations. This initiative is part of a broader effort to ensure that members are actively engaged in safeguarding patient information and OPTN systems against emerging threats.

Summary of Discussion:

Mr. Carnahan outlined the elements of the security attestation, including the expectations for members to formally confirm that their organizational practices align with established security protocols. These protocols include access control mechanisms, data protection measures, incident response plans, and regular risk assessments. It was emphasized that the attestation is not intended to be a punitive or burdensome requirement, but rather a proactive exercise in accountability and due diligence.

He also shared insights gathered during the initial phase of attestation collection. It was noted that while a significant number of organizations had already completed the process, there remained a subset of members who had either submitted incomplete documentation or had not yet responded. He highlighted several common issues encountered in the submissions, such as insufficient detail regarding internal security practices, lack of clarity around user access controls, and inconsistencies in documenting compliance with minimum security standards.

To address these gaps, the support resources available to members, including guidance documents, checklists, and consultation availability through the Governance, Risk, and Compliance team. He also emphasized the importance of designating appropriate points of contact within each organization who possess the necessary knowledge and authority to complete the attestation accurately.

The committee discussed the timeline for full compliance, reiterating the final submission deadline and the potential consequences of noncompliance, including system access limitations. It was underscored that while the OPTN aims to take a collaborative and educational approach, the integrity and security of the system must remain a top priority.

5. Closed Session

The committee met in a closed session.

6. Adjourn

The meeting adjourned.

Upcoming Meetings

- May 8, 2025

Attendance

- **Committee Members and Advisors**
  - Andrew Kao
  - Colleen McCarthy
  - Daniel Yip
  - Edward Hollinger
  - Glen Kelley
  - Kelley Hitchman
  - Lori Markham
  - Laura Butler
  - Patrick Northup
  - Paul Connelly
  - Sandra Amaral
- **OPTN Executive Director**
  - Rexanah Wyse Morrissette
- **HRSA Representatives**
  - Heather Myers
  - Jamie Juarez
  - Jim Duff
  - Nikki Ramos
  - Manjot Singh
  - Mesmin Germain
  - Patrick Mauro
  - Vinay Vuyyuru
- **UNOS Staff**
  - Bryan Carnahan
  - Jonathan Moore
  - Matt Cafarella
  - Sara Rose Wells
  - Tynisha Smith