

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
November 10, 2016
Conference Call**

**Sue Dunn, RN, BSN, MBA, Chair
Jennifer Milton, BSN, CCTC, MBA, Vice Chair**

Discussions of the full committee on November 10, 2016 are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. None

Committee Projects Pending Implementation

2. None

Implemented Committee Projects

3. None

Other Significant Items

- 4.

5. **Dr. David Klassen, UNOS CMO, reports on the IOM meeting regarding *Issues in Organ Donor Intervention Research* held on September 29, 2016.**

Dr. Klassen's presentation covered the recent Institutes of Medicine (IOM) meeting, which was of particular interest to the POC because they voted at its last conference call to recommend approval of a new Ethics committee project for a guidance document on the same subject. The Executive Committee later did not approve the project because of concerns of conflict with the IOM work regarding Organ Donor Intervention Research, and the Ethics Committee asked for the report from Dr. Klassen to better understand the IOM process.

Dr. Klassen reported that there is a paucity of research trials in the field of donor management, so that IOM believes this is an important subject to study. There are logistical, regulatory, and ethical barriers to performing these types of research trials and a lack of clarity in regulatory oversight of research on donor organs.

Dr. Klassen's report also identified the main policy roadblocks for advancing organ donor research, including:

- Deceased donors are not human subjects and thus not subject to oversight by the OHRP or IRBs
- Organ allocation after donor intervention complicates issues of informed consent and adherence to allocation policy
- Unclear mechanism for safety monitoring of targeted and untargeted organs

Also, a Public Citizen complaint in April 2016 that followed a HRSA funded study to investigate therapeutic hypothermia in deceased organ donors brought to the forefront the need for reviewing the ethics and policy issues in organ donor research.

The IOM committee was funded in 2016 and the first meeting was the one that Dr. Klassen attended on September 29, 2016. The next meeting is scheduled for December 14, 2016.

The Ethics Vice Chair reiterated her opinion that their work on a white paper exploring these issues would not be in conflict with the IOM work. A POC member asked about the process for bringing On Hold or Cancelled projects back to the committee for review, and the Chair responded that they can be brought back and go through the usual process.

6. Committee Project Portfolio – preview of report to Executive Committee

POC Chair, Sue Dunn, gave a brief overview of the report that she will provide to the Executive Committee at the December board meeting. The report summarized the POC's recommendations to the Executive Committee on new committee projects since the last Board meeting in June 2016.

Ms. Dunn reported that the POC recommended four projects for approval:

1. Revisions to Pediatric Emergency Membership Exception
2. Ethical Considerations for Experimental Manipulations of Organ Recovered from Deceased Donors - Ethics Committee
3. Maximum Allowable BMI for Kidney/Pancreas Waiting Time - Pancreas Committee
4. OPTN Bylaw Revisions to Appendix L - Membership & Professional Standards Committee

The POC put the Reduce Pediatric Liver Waiting List Mortality project from the Pediatric Committee *On Hold*, because although the POC supported the substance of the project, there were significant concerns about resources due to liver redistricting and related projects.

The POC did not recommend for approval the Informing Potential Living Donors about Recovery Centers with Different Eligibility Criteria from the Living Donor Committee. The POC felt that this project still needed to be "fleshed out" and that important milestones were missing and that important stakeholders were not identified.

She further summarized that the Executive Committee accepted each of the recommendations we made about the six projects, except for the Ethical Considerations for Experimental Manipulations of Organ Recovered from Deceased Donors. The Executive Committee, after consideration of the upcoming IOM review and discussion, decided not to approve this project at present.

So the final count of projects after POC and Executive Committee review equals: 3 approved, 2 not approved, and 1 project *On Hold*.

7. Spring 2017 In-person Meeting Update

The POC agreed that the next in-person meeting will be held in Richmond, VA on May 15-16, 2017. The group expressed some concern of travel time for those west of the Mississippi, particularly given that there are so few direct flights to Richmond. However, the Committee members agreed that it would be good to have the new Vice Chair orientation on Monday, May 15 followed by the full committee meeting on Tuesday, May 16 and that being in Richmond would provide opportunities for Vice Chairs to meet with their liaisons and UNOS leadership.

Upcoming Meetings

- December 15, 2016 12:00 PM EST Conference Call
- January 18, 2017, 2:00 PM EST Conference Call
- February 16, 2017 12:00 PM EST Conference Call