

**OPTN Operations and Safety Committee  
Donor Testing Requirements Workgroup  
Meeting Summary  
April 16, 2025  
Conference Call**

**Annemarie Lucas, MHSA, Chair**

## **Introduction**

The OPTN Operations and Safety Committee’s Donor Testing Requirements Workgroup (the Workgroup) met via WebEx teleconference on 04/16/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Review and Finalize Workgroup Recommendations
3. Closing Remarks

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

### **1. Welcome and Announcements**

The Chair welcomed the members and reviewed the agenda for the meeting.

### **2. Review and Finalize Workgroup Recommendations**

The Workgroup reviewed draft policy and guidance language based on the recommendations developed by the Workgroup to date.

#### Summary of discussion:

Decisions for each section of the policy are delineated below.

The Workgroup were provided with an overview of the policies reviewed. OPTN Policy 2.9: *Required Deceased Donor Infectious Disease Testing* as the only policy the Workgroup made no policy or guidance recommendations for this policy.

The following is an overview of the policy recommendations made by the Workgroup and their discussions:

#### *Policy 2.8 Required Deceased Donor General Risk Assessment*

#### **Workgroup Recommendation:**

- Specify that for urinalysis, “the host OPO will make a reasonable effort to obtain on a donor with renal disease.”

A member suggested “renal impairment” or “impaired renal function” rather than “renal disease” since donors may not have an official diagnosis of renal disease when under evaluation by the organ procurement organization (OPO). Another member commented that the recommendation to add this language is to convey that if the donor has no urine output, the urinalysis may be challenging to obtain. The donor may not necessarily have a disease; therefore, “impaired renal function” may be more

reflective to what the Workgroup wants to convey. Members agreed with replacing “renal disease” with “impaired renal function.”

#### *Policy 2.10 Additional Deceased Donor Testing*

##### **Workgroup Recommendations:**

- Remove language, “after receiving the test results”
- Modify language to “within 24 hours of the OPO being made aware of the test result”

Members agreed with clarifying the language to indicate that results of any additional testing must be reported “within 24 hours of the OPO being made aware of the test result.”

#### *Policy 2.11 Required Deceased Donor Information*

Members agreed that this policy does not require delineation between information that is required and information that the host OPO “must make reasonable efforts to obtain” and that their recommendations to incorporate this language applies to the organ-specific sections of Policy 2.11. No changes were made to this policy.

##### *Policy 2.11.A Required Information for Deceased Kidney Donors*

##### **Workgroup Recommendations:**

- Removal of language “excluding donors less than 18 years old” (item 6)
- **New Consideration (to mirror lung policy language):** Modify first paragraph of policy to “The host OPO must ensure that all the following additional information for all deceased kidney donors is obtained and provided with the kidney donor offer:”

An member commented that last year, their OPO started requiring transplant programs to accept kidneys prior to operating room (OR). Policy 5.6.B *Time Limit for Review and Acceptance of Organ Offers* states that, “Once the host OPO has provided all the required deceased donor information according to OPTN Policy 2.11: *Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour” with either an organ offer acceptance or refusal. The member continued to explain that their OPO considers biopsy to be included in “recovery information” and require transplant programs to accept organs prior to going to the OR (kidneys specifically) with still anatomy and all recovery information pending.

The Workgroup discussed whether there should be any changes to the biopsy requirements for donors less than 18 years old. The member said there is likely little benefit to performing a biopsy on a younger donor. Generally, unless a donor less than 18 years old has kidney disease to begin with, a biopsy probably won’t provide much information. The member continued by stating that they would be in support of the recommended policy change so as not to limit the OPO’s ability to biopsy the kidney; the member was also supportive of moving forward with guidance as well. Members discussed that the policy language excluding donors less than 18 years old from the biopsy requirements should remain, and guidance could be provided on when it may be appropriate to perform a biopsy on a donor less than 18 years old.

OPTN Contractor staff clarified that removing this language would expand when the OPO would have to do a biopsy, so if there were situations where donors less than 18 years old when an OPO should not be required to do a biopsy should be specified in policy. A member asked for clarification that if the language “excluding donors less than 18 years old” were removed, would OPOs then be required to biopsy donors who are less than 18 years old? OPTN Contractor staff responded that OPOs would be

required to biopsy donors less than 18 years old if they met any of the criteria outlined in policy. The member then asked what the purpose of guidance to the biopsies of donors younger than 18 years old; if the language were removed, the OPOs would be mandated to biopsy if one of the criteria listed were met. The intent of removing the exclusion of donors less than 18 years old is to allow the OPOs the ability to biopsy the kidney if they met something that would be outlined in the guidance document.

Another member commented that the removal of language of excluding biopsy of donors less than 18 years old would mean that OPOs would need to biopsy if certain criteria is met versus guidance language that would provide more flexibility for OPOs to decide when to biopsy a donor less than 18 years old.

A member pointed out that current policy does not prohibit an OPO from performing a biopsy on kidney that does not meet the criteria outlined, which is appropriate. The Workgroup Chair summarized that the Workgroup's recommendation would be to not make any changes to the policy language and instead to provide recommendations in guidance for when a biopsy for donors less than 18 years old should be considered.

The Workgroup Chair then asked members if there was agreement with consideration in modifying the first paragraph of the policy to "The host OPO must ensure that all the following additional information for all deceased kidney donors is obtained and provided with the kidney donor offer:" A member stated that there is a timing issue depending on when an offer occurs. An OPO may not have biopsy results for kidneys and the OPO may not have all the data that is being displayed in policy at the time of an offer as these tests would start prior to the OR. Another member agreed with this and voiced concerns that if this was included in the kidney policy language, this would run the risk of unintended consequence of kidney allocation post cross clamp taking longer and also kidney allocation prior to cross clamp not being done because none of these results will be available prior to recovery. The member stated that HLA is the only test result that would be available early on and all other tests outlined in policy would be reported subsequently. OPOs are unable to run a kidney list without HLA, so it is always reported prior to the offer.

Another member asked if there was a reason to have a point in time specified in policy. The member suggested the following language, "The host OPO must provide the following information for all deceased kidney donors:". There are too many variables that can create challenges if the policy were to be specified further.

#### *Policy 2.11.B Required Information for Deceased Liver Donors*

##### **Workgroup Recommendations:**

- Add language "The host OPO must make reasonable efforts to obtain the following information for all deceased donors. If the host OPO obtains any of the following information, it must be provided with the donor offer. If the host OPO cannot obtain this information, the host OPO must document the reason and make this documentation available to the OPTN on request."
- Remove "direct bilirubin" (item 2c)
- **New Consideration (to mirror lung policy language):** "The host OPO must ensure that all the following additional information for all deceased liver donors is obtained and provided with the liver donor offer:"
- **New Consideration:** add "and imaging" to items 3 and 4

The Workgroup discussed that the policy should not require pre-procurement biopsies and supported the existing policy language specifying that pre-procurement biopsies should be reported if performed. A member noted that from previous Workgroup discussions, OPOs will sometimes upload images of the

biopsies and sometimes they have them but do not upload them. The member recommended the language to be “Pre-procurement biopsy results and imaging, if performed” and keeping it as currently placed as item 3 that an OPO must ensure that this information is obtained and provided with the liver donor offer (versus the host OPO making reasonable efforts to obtain this information).

A member stated that there is no need to delineate what tests outlined in this policy as it is believed that it is clearly stated in current policy already. The current policy outlines those tests that are needed within 12 hours of the offer, while items 3 and 4 are less restrictive in that the host OPO would report that information if able to obtain.

#### *Policy 2.11.C Required Information for Deceased Heart Donors*

##### **Workgroup Recommendations:**

- Add language “The host OPO must make reasonable efforts to obtain the following information for all deceased donors...”
- Remove language, “if available” (item 1)
- Add language, “imaging” (item 1)
- Add “troponin value thresholds and cut off value”
- **New Consideration (to mirror lung policy language):** “The host OPO must ensure that all the following additional information for all deceased heart donors is obtained and provided with the heart donor offer.”

A member said that OPOs should be required to report an electrocardiogram for deceased heart donors. Members agreed. A member said an interpretation of the echocardiogram is not needed if the imaging is provided but interpretation of the echocardiogram should be provided. Members supported requiring imaging for the electrocardiogram and removing the requirement for interpretation and making this a hard requirement for deceased heart donors by removing the “if available” language. The OPTN Contractor staff summarized that the language would read, “12-lead electrocardiogram imaging”, all of the testing requirements outlined would be required and there would be no language added to delineate any testing specifying that the host OPO make reasonable efforts to obtain. The Workgroup agreed with this.

The Workgroup discussed adding “troponin value thresholds and cut off value” to the policy as a requirement for all deceased heart donors. A member said the Workgroup needs to establish the upper limit of normal, which becomes the cut-off value. Another member suggested this mirroring language related to lipase for pancreas.

A member said what they often see is a donor starts out in one hospital and transfers to another hospital or donor recovery center, and different troponin values are reported. The member said it can be challenging to determine which troponin value was drawn from which institution. The member said that troponin should be required and their program’s surgeons always ask for it, and the transplant program makes several calls for each donor to obtain the troponin. The member added that this information is especially important to obtain if there was downtime.

##### Next steps:

The draft policy language and guidance will be updated to reflect the Workgroup’s discussions.

### **3. Closing Remarks**

The Workgroup will reconvene in May to complete review of the proposed policy and guidance changes.

**Upcoming Meeting**

- Wednesday, May 21, 2025 (Teleconference)

## Attendance

- **Workgroup Members**
  - Annemarie Lucas, Workgroup Chair
  - Laurine Bow
  - Lara Danziger-Isakov
  - Dan DiSante
  - Kaitlyn Fitzgerald
  - Hanh Khuu
  - Dean Kim
  - Kimberly Koontz
  - Shehzad Rehman
  - Irma Sison
  - Malay Shah
  - Norihisa Shigemura
  - Elizabeth Shipman
  - Heather Miller Webb
  - Jessica Yokubeak
  - Chuck Zollinger
- **UNOS Staff**
  - Betsy Gans
  - Cass McCharen
  - Rob McTier
  - Sharon Shepherd
  - Kaitlin Swanner
  - Niyati Upadhyay
  - Joann White