

## *Notice of OPTN Data Collection*

# Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

<b>Sponsoring Committee:</b>	<b>Organ Procurement Organization</b>
<b>Data Instruments Affected:</b>	<b>OPTN Donor Data and Matching System</b>
<b>Public Comment:</b>	<b>August 2, 2022 – September 28, 2022</b>
<b>Board Approved:</b>	<b>December 5, 2022</b>
<b>Effective Date:</b>	<b>Pending implementation and notice to OPTN members</b>

### **Purpose of New Data Collection**

The purpose of this data collection is to streamline communication of DCD donor information between OPOs and transplant hospitals, in order to improve offer evaluation and allocation efficiency. The proposed data collection will support more efficient donor evaluation, as this information will be easily accessible in the OPTN Donor Data and Matching System. It aims to increase overall allocation efficiency by reducing cold ischemic times and supporting increased DCD transplantation.

### **Proposal History**

This proposal is one of several projects developed to promote the efficiency of organ placement in an effort to increase the number of transplants and promoting the efficiency of the OPTN. These projects included concurrent work on organ offer filters, addressing the use of provisional yes acceptances, and proposing changes to the OPTN Donor Data and Matching System.


This proposal was widely supported during public comment. Based on feedback, the Committee made several changes to the original proposal. The OPTN Board of Directors approved the proposed data elements at the December 5, 2022 meeting.

### **Summary of Changes**

This proposal adds data elements to the OPTN Donor Data and Matching System that will provide key clinical information related to donor progression of death, warm ischemic time, cold ischemic time, and the use of normothermic regional perfusion (NRP).

### **Implementation**

This proposal will provide additional data fields in the OPTN Donor Data and Matching System. This may require OPOs to update their electronic donor records to allow for updated DCD information on active donor cases. OPO staff should become familiar with these changes to data required by the OPTN.

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This proposal is not anticipated to affect the operations of transplant hospitals; however, transplant hospital staff should be familiar with the availability of this additional DCD donor information when evaluating organ offers.

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. As these data are proposed to be collected under §121.11(b)(2) of the OPTN Final Rule, after OPTN Board approval they must be submitted for Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995. Once OMB-approved, the data will be maintained according to the OPTN System of Records Notice. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

## Affected Data Collection

### OPTN Donor Data and Matching System Additions

- Controlled DCD, yes/no
- Withdrawal of life-sustaining medical support, date/time
  - Format: MM/DD/YYYY and HH:MM
- Cessation of circulation, date/time
  - Format: MM/DD/YYYY and HH:MM
- Abdominal aorta flush time (in situ), date/time
  - Format: MM/DD/YYYY and HH:MM
- Portal vein flush time (in situ), date/time
  - Format: MM/DD/YYYY and HH:MM
- Thoracic aorta flush time (in situ), date/time
  - Format: MM/DD/YYYY and HH:MM
- Pulmonary artery flush time (in situ), date/time
  - Format: MM/DD/YYYY and HH:MM
- Oxygen saturation (SpO<sub>2</sub>) - Serial
  - Format: Text field (Range: 0-100)
  - Format: MM/DD/YYYY and HH:MM
- NRP recovery, yes/no
- Initiation of NRP, date/time
  - Format: MM/DD/YYYY and HH