

## *Notice of OPTN Data Collection Changes*

# Standardize Kidney Biopsy Reporting and Data Collection

<b>Sponsoring Committee:</b>	<b>Kidney Transplantation</b>
<b>Data Collection Affected:</b>	<b><i>OPTN Donor Data and Matching System Data System for the Organ Procurement and Transplantation Network – Deceased Donor Registration Form (DDR)</i></b>
<b>Public Comment:</b>	<b>January 27, 2022 – March 23, 2022</b>
<b>Board Approved:</b>	<b>June 27, 2022</b>
<b>Effective Date:</b>	<b>Pending implementation and notice to OPTN members</b>

### **Purpose of Data Collection Changes**

Procurement biopsies are increasingly prevalent, with biopsies performed on more than half of all deceased donor kidneys recovered for transplant. Despite this prevalence, there is significant variation in biopsy practice, and recent literature has shown considerable variation in the quality and reliability of procurement biopsies. In particular, the quality and comprehensiveness of analysis of biopsy results vary based on geography and pathologist experience, with inconsistencies in both the reporting of the results and the specific biopsy parameters reported. This policy will standardize and improve biopsy reporting and data collection by establishing a standard set of biopsy parameters for Organ Procurement Organizations (OPOs) to provide to transplant programs and the OPTN. This proposal will require OPOs to provide these specific biopsy characteristics, which are critical to inform offer evaluation and appropriate acceptance practices for transplant programs evaluating those offers. Standardization of biopsy reporting will reduce inconsistencies in quality and comprehensiveness of biopsy analysis among OPOs, minimize the need for transplant hospitals that accept deceased donor kidney offers to perform their own biopsy analysis, and streamline reporting of biopsy results, thus improving allocation efficiency.

### **Proposal History**

In 2020, the OPTN Policy Oversight Committee's (POC) Biopsy Standards and Practices Workgroup identified ongoing inconsistencies in biopsy practices and quality of analysis as a major hurdle to greater allocation efficiency. The POC tasked the OPTN Kidney Transplantation Committee with the development of a standard pathology form, to identify those characteristics and data points most useful to inform offer acceptance and thereby increase allocation efficiency. The Kidney Committee formed the Biopsy Best Practices Workgroup (the Workgroup) with a subject matter expert in renal pathology and representation from the OPTN Kidney, Organ Procurement Organization (OPO), Liver and Intestinal Organ, and Data Advisory Committees. The Workgroup collaborated throughout 2021 to produce two formal proposals, *Standardize Biopsy Reporting and Data Collection* and *Establish Minimum Kidney Donor Criteria to Require Biopsy* for the Winter 2022 Public Comment period. The Committee

considered community feedback collected during public comment, and incorporated an additional element to capture arteriolar hyalinosis, allowed for an “unknown” response option for several data elements, and reduced granularity of response options for certain elements in order to improve reproducibility. The Board approved these data collection changes on June 27, 2022.

### Summary of Changes

OPTN Policy 2.11.A: *Required Information for Deceased Kidney Donors* requires OPOs to report all biopsy results when a procurement kidney biopsy is performed for deceased donor kidneys. These updates to data collection will require the OPO to report this information according to the following data elements in both the OPTN Donor Data and Matching System and the DDR form in the Data System for Organ Transplantation and Procurement Network:

Data Element	Response Options				
Biopsy Type	Wedge		Core Needle		
Tissue Preparation Technique	Frozen		Formalin-Fixed Paraffin Embedded		
Number of Glomeruli	_____				
Number of Globally Sclerotic Glomeruli	_____				
Percent Globally Sclerotic Glomeruli	_____ %				
Nodular Mesangial Glomerulosclerosis	Absent	Present		Unknown	
Interstitial Fibrosis and Tubular Atrophy (IFTA)	<5%	5-25%	26-50%	>50%	Unknown
Vascular Disease	None: <10%	Mild: 10-25%	Moderate: 26-50%	Severe: >50%	Unknown
Arteriolar Hyalinosis	None	Mild to Moderate (1 arteriole)	Moderate to Severe (>1 arteriole)	Severe – multiple or circumferential	Unknown
Cortical Necrosis	Absent		Present: _____ %		Unknown
Fibrin Thrombi	Absent		Present: _____ %		Unknown
Other Comments:	_____				

Specific modifications to current elements, the additional elements, and data definitions are detailed below.

### Implementation

#### *Organ Procurement Organizations*

This policy will require OPOs to coordinate with pathology services and colleagues to ensure results are reported per the standardized report, through request or the provision of sample forms. This policy will also require OPOs to report this data in the OPTN Donor Data and Matching System, to streamline communication of biopsy results to evaluating transplant programs. Administrative burden of data entry into the Deceased Donor Registration Form (DDR) may be mitigated by the alignment of biopsy

reporting on the DDR and in the OPTN Donor Data and Matching System. OPOs utilizing biopsy reporting in a donor electronic medical record (EMR) may have implementation efforts associated with reformatting those EMRs and reconfiguring APIs to align with updated biopsy data collection in the OPTN Donor Data and Matching System.

### *Transplant Hospitals*

Transplant hospitals and offer-evaluating clinicians and staff should review and understand the information provided in the standardized biopsy report. Transplant hospital staff will need to utilize educational materials on the standardized biopsy data elements, what they capture, and related education on biopsy in holistic review of donor kidney organ offer.

### *OPTN*

This policy will require implementation in the OPTN Computer System. The OPTN plans to distribute educational materials, and is seeking to release a sample pathology report for OPO use and integration into current procurement kidney pathology practices. The OPTN will also communicate these data collection changes and produce monitoring reports at six months, 12 months, and 24 months post-implementation.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN or collected in a different format. The OPTN Contractor has agreed that data collected pursuant to the OPTN’s regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the modifications to the OPTN Donor Data and Matching System data collection and DDR form will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

## Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

### Proposed Modifications to Biopsy Data in the OPTN Donor Data and Matching System

Data Element	Current State	Proposed Changes
<b>Biopsy Type</b>	Biopsy type – Needle, Wedge	No proposed changes
<b>Tissue Preparation Technique</b>	Field not present in current state	Response options include Frozen Section, Formalin-Fixed Paraffin-Embedded Section (FFPE)
<b>Number of Glomeruli</b>	Glomeruli count – numeric field response	Number of Glomeruli – numeric field response
<b>Number of Globally Sclerotic Glomeruli</b>	Field not present in current state	Response options include a numeric field
<b>Percent Globally Sclerotic Glomeruli</b>	Percent Glomerulosclerosis – numeric percentage field	Percent Globally Sclerotic Glomeruli – numeric percentage field
<b>Nodular Mesangial Glomerulosclerosis</b>	Field not present in current state	Nodular Mesangial Glomerulosclerosis – absent, present, unknown
<b>Interstitial Fibrosis and Tubular Atrophy (IFTA)</b>	Field not present in current state	Interstitial Fibrosis and Tubular Atrophy – less than 5%, 5-25%, 26-50%, greater than 50%, unknown

Data Element	Current State	Proposed Changes
<b>Vascular Disease (Percent Luminal Narrowing of the Most Severely Involved Vessel)</b>	Field not present in current state	Vascular Disease (Percent Luminal Narrowing of the Most Severely Involved Vessel) – None (<10%), Mild (10-25%), Moderate (26-50%), Severe (>50%), unknown
<b>Arteriolar Hyalinosis</b>	Field not present in current state	Arteriolar Hyalinosis – None, Mild to Moderate (1 arteriole), Moderate to Severe (>1 arteriole), Severe (Multiple or circumferential), unknown
<b>Cortical Necrosis</b>	Field not present in current state	Cortical Necrosis – absent, present with numeric percentage field, unknown
<b>Fibrin Thrombi</b>	Field not present in current state	Fibrin Thrombi – absent, present with numeric percentage field, unknown

### Proposed Modifications to Biopsy Data in the Deceased Donor Registration Form (DDR)

Data Element	Current State	Proposed Changes
<b>Biopsy Type</b>	Type of biopsy – Needle, Wedge, or Other Specify (open text field)	Biopsy Type – Needle, Wedge
<b>Tissue Preparation Technique</b>	Field not present in current state	Tissue Preparation Technique – Frozen Section, Formalin-Fixed Paraffin-Embedded Section (FFPE)
<b>Number of Glomeruli</b>	Number of Glomeruli Visualized – Numeric field response	Number of Glomeruli – numeric field response
<b>Number of Globally Sclerotic Glomeruli</b>	Field not present in current state	Number of Globally Sclerotic Glomeruli - Numeric field response
<b>Percent Globally Sclerotic Glomeruli</b>	Glomerulosclerosis percentage – 0-5%, 6-10%, 11-15%, 16-20%, greater than 20%, indeterminate	Percent Globally Sclerotic Glomeruli – percentage field response
<b>Nodular Mesangial Glomerulosclerosis</b>	Field not present in current state	Nodular Mesangial Glomerulosclerosis – absent, present, or unknown
<b>Interstitial Fibrosis</b>	Interstitial Fibrosis – absent, minimal, mild, mild-moderate, severe, unknown	Interstitial Fibrosis and Tubular Atrophy – less than 5%, 5-25%, 26-50%, greater than 50%, unknown
<b>Vascular Disease (Percent Luminal Narrowing of the Most Severely Involved Vessel)</b>	Vascular Changes – absent, minimal, mild, mild-moderate, severe, unknown	Vascular Disease (Percent Luminal Narrowing of Most Severely Involved Vessel – None (<10%), Mild (10-25%), Moderate (26-50%), Severe (>50%), unknown
<b>Arteriolar Hyalinosis</b>	Field not present in current state	Arteriolar Hyalinosis – None, Mild to Moderate (1 arteriole), Moderate to Severe (>1 arteriole), Severe (Multiple or circumferential), unknown

Data Element	Current State	Proposed Changes
<b>Cortical Necrosis</b>	Field not present in current state	Cortical Necrosis – Absent, Present with numeric percentage field, unknown
<b>Fibrin Thrombi</b>	Field not present in current state	Fibrin Thrombi – Absent, Present with numeric percentage field, unknown

### Proposed Data Elements and Definitions

Data Element	Current Definition	Proposed Changes
<b>Biopsy</b>	The process of removing tissue from patients for diagnostic examination	No proposed changes
<b>Biopsy Type</b>	No definition present in current state	The method by which tissue is removed from the patient for diagnostic examination
<b>Tissue Preparation Technique</b>	No definition present in current state	The method by which biopsy material is prepared for histologic examination
<b>Number of Glomeruli</b>	No definition present in current state	The total of all glomerular capillary tufts in the sample, include sclerotic and non-sclerotic tufts
<b>Number of Globally Sclerotic Glomeruli</b>	Field not present in current state	The number of glomeruli exhibiting global (complete) collapse of glomerular capillary walls and consolidation of the glomerular tuft by extracellular matrix, causing capillary luminal obliteration
<b>Percent Globally Sclerotic Glomeruli (Percent Glomerulosclerosis)</b>	The percentage of sclerosis (or hardening) of the glomeruli calculated on biopsy. This pathology usually commences in the juxtamedullary glomeruli and gradually spreads to involve other parts of the kidney, eventually causing kidney failure	The percentage of glomeruli exhibiting global (complete) collapse of glomerular capillary walls and consolidation of the glomerular tuft by extracellular matrix, causing capillary luminal obliteration
<b>Nodular Mesangial Glomerulosclerosis</b>	Field not present in current state	Rounded accumulation of collagenous matrix expanding one or more mesangial areas
<b>Interstitial Fibrosis (IF)</b>	No definition present in current state	The accumulation of fibrous tissue between the tubules
<b>Tubular Atrophy (TA)</b>	Field not present in current state	Shrinkage of tubules with variable thickening of the tubular basement membrane and flattening of the tubular epithelium

Data Element	Current Definition	Proposed Changes
<b>Vascular Disease</b>	No definition present in current state	Fibrous thickening of the intima of arteries, measured by the percent luminal narrowing of the most severely involved vessel
<b>Percent Luminal Narrowing</b>	Field not present in current state	The reduction in diameter of vessel lumens owing to vascular disease
<b>Arteriolar Hyalinosis</b>	Field not present in current state	Arteriolar hyaline thickening
<b>Cortical Necrosis</b>	Field not present in current state	Deaths of cortical cells, typically affecting all three tissue compartments
<b>Fibrin Thrombi</b>	Field not present in current state	Capillary lumen aggregate of coagulated blood containing fibrin and platelets, with or without entrapped cellular elements