

## Notice of OPTN Policy Change

# Establish Minimum Kidney Donor Criteria to Require Biopsy

<b>Sponsoring Committee:</b>	<b>OPTN Kidney Transplantation Committee</b>
<b>Policy Affected:</b>	<b>2.11.A: Required Information for Deceased Kidney Donors</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 Policy Change

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 considerable variation in biopsy practice, with both the donor criteria appropriate for biopsy varying amongst Organ Procurement Organizations (OPOs) and the rate of biopsy amongst OPOs ranging from 22.8 percent of deceased donor kidneys to 77.5 percent, adjusting for donor factors.<sup>1</sup> This policy will standardizes biopsy practices by establishing clear donor criteria in situations where an OPO must perform a procurement kidney biopsy. This policy requires procurement kidney biopsy in situations where the biopsy information is critical to evaluating kidney transplant programs to inform offer evaluation. Standardization of practices will reduce variability among OPOs, streamline communication between transplant hospitals and OPOs, potentially prevent unnecessary biopsies, and improve allocation efficiency. Improving efficiency of offer acceptance will potentially reduce cold ischemic time and potentially reduce organ discards.

### 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 to develop a minimum set of donor criteria appropriate for biopsy. 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, OPO, Liver and Intestinal Organ, and Data Advisory Committees. The Workgroup collaborated throughout 2021 to produce two formal proposals, *Establish Minimum Kidney Donor Criteria to Require Biopsy* and *Standardize Biopsy Reporting and Data Collection* for the Winter 2022 Public Comment period. The Committee considered community feedback collected during public comment, which highlighted concerns regarding access to pathology services in rural areas, and updated the proposal to address these concerns. These updates included the requirement that OPOs make "a reasonable effort" to perform a procurement kidney biopsy, and in the case a biopsy is not

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<sup>1</sup> Lentine et al. "Variation in Use of Procurement Biopsies and Its Implications for Discard of Deceased Donor Kidneys Recovered for Transplantation," *American Journal of Transplantation*, 19 (2019): 2241-2251.

performed, that the OPO document the reason why the biopsy could not be performed. The Board approved these policy changes on June 27, 2022.

## Summary of Changes

This policy establishes the following deceased kidney donor criteria for when OPOs are required to perform a procurement biopsy. OPOs must make a reasonable effort to ensure that a procurement kidney biopsy is performed for all donors meeting any of the following criteria, excluding donors less than 18 years old:

- Anuria, or a urine output of less than 100ml in 24 hours during the most recent hospital admission or in the course of donor management
- Donor has received hemodialysis or other renal replacement therapy during most recent hospital admission or in the course of donor management
- History of diabetes, including hemoglobin A1c (HbA1c) of 6.5 or greater during donor evaluation and management
- KDPI greater than 85 percent
- Donor age 60 years or older
- Donor age 50-59, and meets at least two of the following criteria:
  - History of hypertension
  - Manner of death: Cerebrovascular Accident (CVA)
  - Terminal creatinine greater than or equal to 1.5 mg/dL

In the case that a biopsy is not performed, the OPO must document the reason why a biopsy could not be obtained. This policy does not limit the OPO to only performing biopsy on those donors that meet the proposed criteria.

## Implementation

### *Organ Procurement Organizations*

This policy will require OPOs to perform renal procurement biopsies for deceased kidney donors meeting the proposed criteria. OPOs will need to coordinate with pathology colleagues to ensure pathology staff or services are available to perform the biopsy reading and appropriately report biopsy information to the OPTN. In cases where a biopsy cannot be performed, the OPO must document the reason why.

### *Transplant Hospitals*

Transplant programs will need to be aware of the new requirements for when deceased kidney donors must have procurement biopsies performed, so that biopsy results may be expected and evaluated.

### *OPTN*

The OPTN will communicate this policy change, provide relevant education, and monitor the performance of the policy at six months, 12 months, and 24 months post-implementation.

## Affected Policy Language

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

## 2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Anatomical description, including number of blood vessels, ureters, and approximate length of each
- ~~2. Biopsy results, if performed~~
2. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
3. Injuries to or abnormalities of blood vessels, ureters, or kidney
4. Kidney perfusion information, if performed
5. Kidney laterality
6. Biopsy results, if performed. The host OPO must make reasonable efforts to perform a biopsy on deceased donor kidneys from donors that meet *at least one* of the following criteria, excluding donors less than 18 years old:
  - Anuria, or a urine output of less than 100ml in 24 hours during current hospital admission or in the course of donor management
  - Donor has received hemodialysis or other renal replacement therapy during current hospital admission or in the course of donor management
  - History of diabetes, or HbA1C of 6.5 or greater during donor evaluation or management
  - KDPI greater than 85% at time of original match run.
  - Donor age 60 years or older
  - Donor age 50-59 years, and meets at least *two* of the following criteria:
    - History of hypertension
    - Manner of death: Cerebrovascular Accident (CVA)
    - Terminal serum creatinine greater than or equal to 1.5 mg/dl

If the biopsy is not performed, the host OPO must document the reason and make this documentation available to the OPTN on request.

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