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**NKF Public Comment** 

OPTN Proposal: OPTN Establish Minimum Criteria for Kidney Biopsy Proposal

Thank you for the opportunity to offer commentary on the Organ Procurement and Transplant Network's (OPTN) policy proposal, "Establish Minimum Donor Criteria to Require Biopsy."

We appreciate the OPTN's effort to create benchmarks to mitigate the wide variation of procurement biopsy use. However, the proposal misses the opportunity to develop a mechanism to curtail the use of procurement biopsies not meeting the proposed criteria. Of more significant concern, we believe the absence of consistent evidence correlating procurement biopsies with graft and patient outcomes makes such standardization premature. As a patient advocacy organization, the National Kidney Foundation (NKF) is committed to helping as many kidney failure patients as possible receive a life-saving transplant. Central to that effort is reducing the discard of kidneys that might otherwise be transplantable. Organ utilization is of the utmost importance to NKF as we strive to create policies that avail more kidneys for transplant to the more than 90,000 individuals on the kidney transplant waitlist.

Research has shown that procurement kidney biopsies often contribute to discards<sup>1</sup>. In 2021, NKF spearheaded a transplant research roundtable that revealed nearly half of all recovered kidneys undergo a procurement biopsy<sup>2</sup>, which is known to add costs and increase cold ischemia time to recovered organs. The primary reason for declined organ acceptance is organ quality related to procurement biopsies<sup>3</sup>. It can be easy to misinterpret the results without consistent access to renal-trained pathologists familiar with deceased donor kidney procurement biopsies, which is detrimental to people awaiting a kidney transplant. A study by Lentine *et al.* found that pathologists who lack specialized training in nephrology contribute to the increasing rate of kidney discards<sup>4</sup>.

<sup>&</sup>lt;sup>1</sup> DOI: https://doi.org/10.2215/CJN.07610713

<sup>&</sup>lt;sup>2</sup> DOI: https://doi.org/10.1111/ajt.15325

<sup>&</sup>lt;sup>3</sup> DOI: https://doi.org/10.1681/ASN.2015010023

<sup>&</sup>lt;sup>4</sup> DOI: https://doi.org/10.1681/ASN.2021030403



Further, there is insufficient evidence about the value of procurement biopsies in assessing graft and patient outcomes. Wang *et al.* conducted a systematic review of medical research articles resulting in no consistent link between procurement biopsies and post-transplant outcomes<sup>5</sup>. There are multiple biopsy scoring systems, all of which have had limited validation in predicting graft or patient survival<sup>6</sup>, which further illustrates the possible substandard optimization of this practice.

NKF recommends continued attention to focus specifically on reducing unnecessary procurement biopsies (for example, avoid biopsying low-risk kidneys). We encourage OPTN to engage with experts who study kidney procurement biopsies to better understand the inherent risks and benefits of these biopsies with regard to organ acceptance and to implement policies that increase kidney transplantation.

Sincerely,

Kevin Longino CEO and Transplant Patient Paul Palevsky, MD President

<sup>&</sup>lt;sup>5</sup> DOI: https://doi.org/10.1111/ajt.13213

<sup>&</sup>lt;sup>6</sup> DOI:10.1097/MNH.0000000000000746