



National  
Kidney  
Foundation®

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Office of Infectious Disease and HIV/AIDS Policy  
U.S. Department of Health and Human Services  
Mary E. Switzer Building  
330 C Street SW, Room L001  
Washington, DC 20024  
Attn: ACBTSA – RFI

October 10, 2019

Dear Mr. Berger,

The National Kidney Foundation (NKF) thanks the Office of Infectious Disease and HIV/AIDS Policy for its attention to the impacts of the PHS Guideline on organ allocation and utilization. While we appreciate that the terminology “Increased Risk Donor (IRD)” was never intended to restrict transplantation or exclude specific donors, we believe it is imperative to reduce stigma that can contribute to the discard of lifesaving organs. Accordingly, we support the proposal to remove any specific label to describe donors with risk factors for undetected HIV, HBV, or HCV infection, so long as OPOs communicate risk factors to transplant centers that are then shared with patients and families during transplantation-related informed consent discussions.

The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

Addressing the critical shortage in the number of kidneys available for transplant by reducing the discard of transplantable organs is an NKF priority. A recent report of over 200,000 deceased-donor kidneys found a discard rate of 17.3 percent.<sup>1</sup> In 2017, the National Kidney Foundation convened the Consensus Conference on Decreasing Kidney Discards to discuss strategies to maximize the utilization of kidneys, including those that are considered less than perfect.<sup>2</sup> A subsequent Clinical Transplantation manuscript outlined a set of recommendations and research priorities to improve utilization that included improving

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<sup>1</sup> Mohan, S., Chiles, M. C., Patzer, R. E., Pastan, S. O., Husain, S. A., Carpenter, D. J., ... Cohen, D. J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International*, 94(1), 187–198. doi: <https://doi.org/10.1016/j.kint.2018.02.016>

<sup>2</sup> Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. (2018, October 22). Retrieved October 8, 2019, from <https://www.kidney.org/news/report-national-kidney-foundation-consensus-conference-to-decrease-kidney-discards>.

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provider and patient education on acceptance of higher risk kidneys to prevent delays in acceptance and increasing the number of transplant centers who utilize high-risk organs.<sup>3</sup> While the reasons for discard are multifactorial, we believe that less stigmatizing terminology may contribute to improved patient and provider education and ultimately utilization by allowing for better contextualization of the tradeoffs between the relatively minor risks of donor-derived disease transmission and remaining on the waitlist.

In general, though NKF supports removing any specific label to describe organs from donors with risk factors, we do believe there is a need to come to a consensus around the terminology used to describe less than perfect organs. This terminology should not focus on any single category of risk, but rather should encompass all the clinical and non-clinical risks and benefits associated with imperfect, yet clinically valuable organs. NKF will continue to engage stakeholders in the transplant community to understand what appropriate terminology would be.

NKF applauds the Office of Infectious Disease and HIV/AIDS Policy for undertaking revisions to the PHS Guideline for Reducing Human HIV, HBV and HCV through Organ Transplantation that will minimize its unintended consequences for kidney patients. We would welcome the opportunity to partner with the Office and other HHS stakeholders to discuss consensus terminology for organs that are considered less than perfect. Please contact Miriam Godwin, Health Policy Analyst, at [miriam.godwin@kidney.org](mailto:miriam.godwin@kidney.org) with questions or concerns.

Sincerely,

*Kevin Longino*

Kevin Longino  
CEO and transplant patient

*Holly Mattix Kramer*

Holly Mattix Kramer, MD, MPH  
President

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<sup>3</sup> Cooper, M., Formica, R., Friedewald, J., Hirose, R., O'Conner, K., Mohan, S., ... Pastan, S. (2019). Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clinical Transplantation*, 33(1). doi: <https://doi.org/10.1111/ctr.13419>