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American Society of Transplant Surgeons®

November 9, 2022

Dear Members of the Advisory Committee on Blood and Tissue Safety and Availability:

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to comment on the Advisory Committee on Blood and Tissue Availability (ACBTSA) recommendations for revisions in the requirements applicable to HIV+ / HIV+ transplants. ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

For kidney and liver transplants, the ACBTSA's proposal would remove statutory "NIH Research Criteria and IRB" requirements (with no special restrictions other than the applicable OPTN kidney and liver policies). For all other organs including thoracic organs, the ACBTSA's proposal would remove statutory "NIH Research Criteria" requirements but require the OPTN to develop and implement several new policies intended to ensure the safety and efficacy of these transplants. Among other things, under the proposal, for organs other than kidneys and livers, the OPTN would be required to establish an organ-specific variance for each organ; implement organ-specific candidate criteria and transplant program requirements analogous (but not "identical") to the NIH Research Criteria; implement additional organ-specific OPTN outcomes monitoring; require each center/institution have an IRB-approved protocol that will include measures of outcomes and safety; and, for multiple organ transplants, require adherence to the guidelines of organs with more conservative policies.

ASTS believes that the ACBTSA's approach strikes an appropriate balance between the need to maintain the safety of HIV+ / HIV+ transplants while expanding the availability of such transplants by reducing bureaucratic obstacles. According to a November 2021 review article¹, as of July 2021, there have been 300 kidney and 87 liver transplants within HOPE research studies in the USA. Early HIV+ / HIV+ kidney transplant outcomes show excellent patient survival (100%) and graft survival (92%).

Unfortunately, the number of HOPE donors continues to grow annually but remains lower than projections, and the availability of HIV+ / HIV+ transplantation remains geographically limited. As of July 2021, 35 transplant centers in 21 states had been approved to perform HIV-to-HIV transplants; 19 of these centers are clustered in the eastern United States, and Region 6 still does not have any HOPE-approved transplant centers.

The potential to increase access to these life-saving procedures is substantial. A 2018 survey of 114 US transplant centers regarding planned practice of HIV+ / HIV+ transplantation indicated that fifty transplant centers (43.8%) were planning to perform such transplants, and one survey found that respondents from transplant centers that had already performed a HOPE transplant were more willing to accept HIV + deceased donor organs, suggesting that willingness to accept HIV + organs will likely increase as more HIV+ / HIV+ transplants are performed. For these reasons, we believe that there

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is significant potential for increased performance of HIV+ / HIV+ transplants. The removal of the current NIH Research Criteria has the potential to significantly expand the availability of these life-saving transplants, especially in areas of the country where access is currently limited or non-existent.

We thank you for the opportunity to comment on these draft recommendations. If you have any questions, please contact Emily Besser at Emily.Besser@asts.org.

Sincerely,

A handwritten signature in black ink that reads "William C. Chapman". The signature is written in a cursive style with a large, stylized "W" and a long, sweeping underline.

William Chapman, MD
President, American Society of Transplant Surgeons