

December 12, 2024

Dr. Jonah Odim
Chief, Clinical Transplantation Section
Transplant Branch, National Institutes of Health
U.S. Department of Health and Human Services
5601 Fishers Lane
Room 6B21 - MSC 9827
Rockville, MD 20892-9827

Submitted Electronically at HOPEAct@mail.nih.gov.

**RE: Draft Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity Act
Safeguards and Research Criteria for Transplantation of Organs Infected With HIV**

Dear Dr. Odim:

The American Society of Transplantation (AST), which represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care, appreciates the opportunity to provide comment to the National Institutes of Health (NIH) and Department of Health and Human Services (HHS) regarding this important topic.

AST strongly supported the Congressional development and passage of the HIV Organ Policy Equity (HOPE) Act in 2013. The removal of the previous prohibition on transplantation of organs from persons with human immunodeficiency virus (HIV) has unquestionably been a positive development for the continued advancement of transplantation and, more importantly, for patients infected with HIV in need of a lifesaving donor organ. The AST continues to applaud Congress, HHS, and the NIH for its ongoing support of transplant in both the biomedical research and clinical care arenas.

In accordance with the HOPE Act, NIH patient research criteria and safeguards were developed and issued in 2015. AST has supported and strongly shared the goals of those safeguards to ensure that:

- Research using organs from donors with HIV is conducted under conditions protecting the safety of research participants and the public; and that
- Results of the research provide a basis for evaluating the safety of transplants of organs from donors with HIV in recipients with HIV.

AST NATIONAL OFFICE

1000 Atrium Way, Ste 400 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.581.9604
info@myAST.org • myAST.org

GOVERNMENT RELATIONS

William Aplegate, Director of Government Relations
Polsinelli
1401 I Street NW, Ste: 800 • Washington, DC 20004
202.258.4989 • baplegate@polsinelli.com

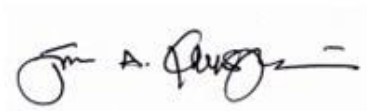
On November 27, 2024, the HHS Secretary and NIH made the determination that participation in clinical research should no longer be a requirement for the transplantation of kidneys and livers from donors with HIV to recipients with HIV. Although AST appreciates and shares the goals of expanding transplantation in this key area, the Society continues to have concerns regarding the Agency's removal of clinical research criteria for living donors for the following reasons:

- The patient population of living donors with HIV who have donated is small,
- Longer term outcomes for HIV-infected living donors have not yet been established; and
- There is a need for more data and scientific evidence to protect living donors with HIV.

Although AST supports continued advancement in the area of HIV-to HIV donation, our Society remains data and evidence driven in our consideration and support of public policy proposals impacting patients. To that end, we support HIV deceased donation to HIV candidates. However, we believe that clinical research studies should be established for HIV living donation to HIV candidates.

Again, thank you for the opportunity to comment on the NIH-HHS Revised HIV Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. Please do not hesitate to reach out to myself or the AST Director of Government Relations, William Applegate (bapplegate@polsinelli.com) should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon A. Kobashigawa". The signature is fluid and cursive, with a horizontal line extending to the right.

Dr. Jon Kobashigawa
President
American Society of Transplantation