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August 12, 2015

Submitted electronically via [HOPEAct@mail.nih.gov](mailto:HOPEAct@mail.nih.gov)

Dr. Jonah Odim, Chief, Clinical Transplantation, Transplantation  
Branch

National Institute of Allergies and Infectious Diseases

National Institutes of Health

5601 Fishers Lane, Room 6B21, MSC 9827

Rockville, MD 20852

RE: HIVMA Comments on NIH's Proposed Safeguards and  
Research Criteria for Implementation of the HIV Organ Policy  
Equity (HOPE) Act

Dear Dr. Odim:

On behalf of the HIV Medicine Association (HIVMA), thank you for the opportunity to comment on the NIH's Proposed Safeguards and Research Criteria for Implementation of the HIV Organ Policy Equity (HOPE) Act. HIVMA represents more than 5,000 clinicians and researchers working on the frontlines of the HIV epidemic in communities across the country. Enactment and implementation of the HOPE Act has been a high priority policy issue for HIVMA from the earliest stages of the policy reform process. We have appreciated the opportunity to provide stakeholder input on development of the HOPE Act research criteria on several occasions leading up to the current proposal.

We find the proposal to be generally sound, and we commend you for the thoughtful work and broad stakeholder consultation that has gone into formulating these recommendations. We understand that as mandated by the HOPE Act, the Secretary, together with the Organ Procurement and Transplantation Network (OPTN), will review the results of scientific research conducted under these criteria to determine whether the OPTN's standards of quality should be further modified and whether some HIV+ to HIV+ transplants should proceed outside the auspices of research conducted under such criteria.

We do have several questions and concerns for your consideration as follows:

1) Stringency of Criteria: While we support adhering to the highest standards of safety and precaution, we are concerned that the stringency of the criteria may make enrollment slow. For example, it may be challenging to document no known history of viral load > 1000 in last 12 months in deceased donors and others. We wonder why a history of viral load > 1000 in the prior 12 months should be exclusionary if someone has been documented suppressed thereafter.

2) Deceased Donor Medical History: We are concerned about the feasibility of obtaining all of the required medical history information in a timely fashion from the deceased donors. We are concerned about discarding useful organs especially on long holiday weekends or if the primary physician is not available to provide information. Perhaps a contingency should be allowed by the accepting institution to accept or decline the organ based upon the information available.

3) Patient Advocates: Although it adds another layer of complexity to the process of conducting HIV+ to HIV+ transplants, we agree that the use of patient advocates is a necessary step to ensure that patients are fully informed and supported in making medical decisions with their physicians.

We are encouraged to see this important step in the process of implementing the HOPE Act moving forward, so that these life-saving transplants can begin under a sound research protocol design. Please count on us as a resource as you work to finalize this proposal. We can be reached through HIVMA Senior Policy Officer, Kimberly Miller at [kmiller@hivma.org](mailto:kmiller@hivma.org).

Sincerely,

A handwritten signature in black ink, appearing to be 'CDR', with a horizontal line extending to the right.

Carlos del Rio, MD, FIDSA  
Chair-Elect, HIVMA Board of Directors