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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity Act Safeguards and Research Criteria for Transplantation of Organs from Donors with HIV

AGENCY: Department of Health and Human Services, National Institutes of Health.

ACTION: Final notice.

SUMMARY: Kidney and liver transplants from donors with HIV no longer require institutional review board (IRB)-approved research protocols or compliance with HHS research criteria per a November 27, 2024, final rule. Through this notice, the U.S. Department of Health and Human Services (HHS)announces the publication of this accompanying Final Revised Safeguards and Research Criteria for Transplantation of Organs from Donors with HIV to apply to non-kidney and non-liver organs from donors with HIV for transplantation in recipients with HIV. Under the HOPE Act, these transplants must still occur under an IRB-approved research protocol that is compliant with federal regulations governing human subjects' research. The goal of this research is to increase knowledge about the safety, efficacy, and effectiveness of transplants other than liver and kidney, from donors with HIV, thereby expanding access to organs for patients with HIV in need of transplants. HHS published Draft Revised Safeguards and Research Criteria on December 12, 2024. A summary of the public comments and HHS' responses follows. As explained below, NIH adopts revised research criteria as proposed except that NIH removed residual stigmatizing language from the title of the Research Criteria.

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SUPPLEMENTARY INFORMATION:

BACKGROUND

A. HHS Oversight of Organ Allocation and Transplantation

HHS is responsible for overseeing the operation of the nation's OPTN, including assisting in the equitable allocation of donor organs for transplantation. 42 U.S.C. 274(b)(2)(D). The OPTN is a network of transplant centers, organ procurement organizations, and other providers who work collectively to develop, implement, and monitor organ allocation policy and performance of the organ transplant system. The OPTN is also charged with developing policies on many subjects related to organ donation and transplantation, which include establishing standards of quality pertaining to organs procured for use in transplantation. 42 U.S.C. 274(b)(2)(E).

B. HOPE Act Requirements and Implementation

The enactment of the HOPE Act in 2013, Public Law 113–51, eliminated the prohibition in the United States on transplantation of organs from persons with HIV, allowing transplantation of these organs if certain requirements are satisfied. Under the HOPE Act, organs from donors with HIV may be transplanted only in recipients living with HIV prior to receiving such an organ. 42 U.S.C. 274(b)(3)(A). Further, the HOPE Act requires that transplants of HIV-positive organs occur only in recipients with HIV who are participating in institutional review board (IRB)-approved research protocols that adhere to certain criteria, standards, and regulations. 42 U.S.C. 274(b)(3)(B)(i). However, the Secretary may lift the research and IRB requirements if the Secretary has determined that participation in such clinical research, as a requirement for such transplants, is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii).

The HOPE Act outlines the process by which the Secretary may make such a determination under 42 U.S.C. 274(b)(3)(B)(ii). Specifically, the Secretary must routinely review the results of scientific research, in conjunction with the OPTN, to determine whether the results warrant revision of the OPTN standards of quality regarding organs from donors with HIV. If the Secretary determines that those standards of quality should be revised, the Secretary must direct the OPTN to revise the standards. 42 U.S.C. 274f-5(c)(2). The Secretary is also required to revise

the regulatory provision implementing the HOPE Act, 42 CFR 121.6, upon determining that revisions to the OPTN standards of quality are warranted. 42 U.S.C. 274f-5(c)(3).

C. Research Criteria for HOPE Act Transplants

In 2015, NIH published proposed research criteria for HOPE Act transplants in the *Federal Register* and solicited public comment. 80 FR 34912 (June 18, 2015). After consideration of public comments received, NIH published the "Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV" ("2015 Research Criteria"). 80 FR 73785 (November 25, 2015). The goals of the 2015 Research Criteria were to ensure that research using organs from donors with HIV was conducted under conditions protecting the safety of research participants and the public and that the results of this research provide a basis for evaluating the safety of transplants of organs from donors with HIV in recipients with HIV. 80 FR 73785.

INTRODUCTION

The HOPE Act requires the Secretary of Health and Human Services (the Secretary) to develop and publish criteria for research involving transplantation of organs from donors with HIV to recipients with HIV. In 2015, the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS) published the initial Research Criteria applicable to such transplants, which was in effect for all transplants involving organs from donors with HIV as authorized by the HOPE Act. Through a final rule published in the Federal Register on November 27, 2024 (89 FR 93484), the Secretary determined that participation in clinical research should no longer be a requirement for transplantation of kidneys and livers from donors with HIV to recipients with HIV and amended the HHS regulations governing the operation of the Organ Procurement and Transplantation Network (OPTN) to reflect this determination. As a result, HOPE Act transplants involving kidneys and livers from donors with HIV no longer need to comply with the NIH Research Criteria. Given this regulatory change, NIH proposed revised Research Criteria and solicited public comments on such revisions by publication in the Federal Register

on November 27, 2024 (89 FR 93616). NIH proposed deleting aspects of the Research Criteria that are specific to kidney and liver transplantation. NIH made additional proposed changes to the Research Criteria based on its review of scientific evidence and in consideration of prior public feedback concerning the criteria, including comments provided in the recent rulemaking procedure that modified the OPTN regulations. There were 4 public comments to the Draft Revised HOPE Safeguards and Research Criteria. After considering the public comments, NIH now finalizes the Revised HOPE Safeguards and Research Criteria. As explained below, NIH adopts revised research criteria as proposed except that NIH removed residual stigmatizing language from the title of the 2015 Research Criteria.

OVERVIEW OF AND RESPONSE TO COMMENTS

Recipient eligibility criteria

One commenter supported eliminating the organ-specific experience criteria of 5 HIV D-/R+ transplants over 4 years. Per the commenter, this benchmark was too high a bar for U.S. heart and lung transplant programs to satisfy; thereby, prohibiting participation in HOPE Act transplantation. This commenter proposed eliminating the recipient eligibility criteria of an HIV viral load < 50 copies/mL in deference to investigator clinical judgement. NIH chose to maintain the undetectable viral load threshold (<50 copies/mL) that aligns with strong expert opinion from the Guidelines for the use of antiretroviral agents in adults and adolescents with HIV: Transplantation in people with HIV current as of 24 September 2024, *https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/transplantation*. This criteria, which applies to transplants involving donors with HIV, does not preclude transplant programs from listing suitable recipients for organs from donors without HIV.

Removal of clinical research criteria for living donors with HIV

One commenter raised concerns over removal of clinical research criteria for living donors with HIV given needs for longer term outcome data. As described above, the final rule issued by the

Secretary has removed the mandated IRB-approved research protocol requirements for HOPE Act kidney and liver transplantation. Living heart and lung donors with HIV are rare occurrences in today's transplant practice. In the event of an intended living donation other than liver and kidney from a person with HIV, we include protections for living donors in the Revised Research Criteria. The revised criteria provide that for such transplants, the deceased donor eligibility criteria will apply. Further, the OPTN collects data on all living donors and transplants, which allows for additional oversight.

Removal of stigmatizing language (e.g., donors infected with HIV)

One commenter requested the removal of residual stigmatizing language from the title of the 2015 Research Criteria, which has been modified in this final document.

Elimination of Mandatory Pre-Implantation Donor Biopsies

This commenter endorsed the elimination of mandatory pre-implantation donor biopsies, since this is not routinely required for solid organ transplants, and the trend towards standardizing the evaluation of donors with HIV to that of donors without HIV.

A final commenter supported the proposed changes to Research Criteria for HOPE Act kidney and liver transplants and applauded measures taken to improve kidney transplant access for people with HIV.

CONCLUSION

HHS appreciates the time and effort responding to the Request for Comments. The comments represented the efforts of truly dedicated individuals and organizations in transplantation. The deliberations over the last 3 years and the responses surrounding the NPRM and the Draft Revised Research Criteria were helpful in completing the Final Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs from Donors with HIV.

CHANGES TO THE 2015 RESEARCH CRITERIA

NIH has made several changes to the 2015 Research Criteria to reflect the Secretary's determination, published by regulation on November 27, 2024 that HOPE Act kidney and liver transplants are no longer required to be conducted as research subject to the 2015 Research Criteria, and to continue to further the goals shared in 2015 with respect to HOPE Act transplants of other organs from donors with HIV that remain subject to the Research Criteria. NIH has removed the requirements from the 2015 Research Criteria applicable to HOPE Act kidney and liver transplants.

NIH has also made other changes to the 2015 NIH Research Criteria for conducting HOPE Act transplants of organs other than kidneys and livers (primarily heart and lung transplants) in IRB-approved research. These changes are intended to accelerate research, ensure research participant safety, and maintain stakeholder confidence in clinical research conducted under the HOPE Act. Notable revisions include the elimination of i) the transplant program experience requirement of five organ-specific transplants of organs from a donor without HIV in a recipient with HIV conducted over 4 years; ii) mandated pre-implant biopsies; and iii) the requirement for HIV independent advocates for living donors with HIV and recipients with HIV. Other organs (including multi visceral organs such as small intestine, stomach, liver, pancreas and colon) and multi organ transplants (e.g., heart-kidney) must comply with the Revised Research Criteria for inclusion of any non-kidney or non-liver organs from donors with HIV and subject to IRB approval.

The revisions to the 2015 Research Criteria are as follows:

Final Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs from Donors With HIV

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TABLE 1. FINAL REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV

REFERENCES

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CD4	Cluster of differentiation 4
D-	Donor Human Immunodeficiency Virus negative
D+	Donor Human Immunodeficiency Virus positive
HBV	Hepatitis B virus
HCT/Ps	Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HIV-	Human Immunodeficiency Virus negative (using serology and/or nucleic acid testing using FDA-licensed, approved or cleared devices)
HIV+	Human Immunodeficiency Virus positive (using serology and/or nucleic acid testing using FDA-licensed, approved or cleared devices)
HOPE Act	HIV Organ Policy Equity Act
HRSA	Health Resources and Services Administration
IRB	Institutional review board
NIH	National Institutes of Health
NPRM	Notice of proposed rule making
OI	Opportunistic infection
OPO	Organ procurement organization
PML	Progressive multifocal leukoencephalopathy
R-	Recipient HIV negative
R+	Recipient HIV positive
RNA	Ribonucleic acid
SOPs	Standard operating procedures

Definitions

Antiretroviral therapy (ART) resistance	When an HIV strain develops drug resistance and/or genetic mutations associated with drug resistance.
HIV superinfection	Systemic HIV superinfection is defined as the detection of HIV viral sequences that phylogenetically cluster with the donor's viral population at two or more time points in circulating blood cells, plasma, or recipient tissues other than the allograft.

Suppressed viral load	HIV RNA below 50 copies per mL with current technology at time of publication of this research criteria document.

The NIH Research Criteria are set forth in six broad categories (Donor Eligibility, Recipient Eligibility, Transplant Hospital Criteria, Organ Procurement Organization (OPO) Responsibilities, Prevention of Inadvertent Transmission of HIV, and Study Design/Required Data Elements and Outcome Measures). Table 1 summarizes the Final Revised HOPE Act Research Criteria in each category and compares them to the 2015 Research Criteria.

Table 1. Final Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs from Donors with HIV.[1]

Category	Previous Criteria	Revised Criteria [No longer pertains to kidney and liver transplants[1]]
Donor Eligibility		
All deceased donors with HIV	No evidence of invasive opportunistic complications of HIV infection. Pre-implant donor organ biopsy. Viral load: no requirement.	No evidence of invasive opportunistic complications of HIV infection. There is no requirement for a pre-implantation biopsy.* Viral load: no requirement.
Deceased donor with known history of HIV and prior antiretroviral therapy (ART)	The study team must describe the anticipated post-transplant antiretroviral regimen(s) to be prescribed for the recipient and justify its conclusion that the regimen will be safe, tolerable, and effective.	The study team must describe the anticipated post-transplant antiretroviral regimen(s) to be prescribed for the recipient and justify its conclusion that the regimen will be safe, tolerable, and effective.
Living donor with HIV	Well-controlled HIV infection defined as: • Cluster of Differentiation 4 (CD4) + T-cell count ≥500/µL for the 6-month period before donation • HIV-1 ribonucleic acid (RNA) <50 copies/mL	Thoracic Organs Exception: The living donor standards are not relevant for thoracic organ transplant except in the rare instances of living donor lung transplant or "domino" heart transplant. In such circumstances, the

[1] Consistent with the final rule amending the OPTN regulations, transplants using kidneys and livers from donors with HIV no longer need to comply with the HOPE Act Research Criteria. When multiple organs from donors with HIV are implanted simultaneously (e.g., dual heart-kidney or dual lung-kidney), the Research Criteria apply to such multiple organ transplants if the transplant of any of the organs are subject to the revised Research Criteria. For example, while a kidney transplant from a donor with HIV no longer is required to be conducted in accordance with the Research Criteria, a dual heart-kidney or dual lung-kidney transplant with organs from donors with HIV is required to be conducted in accordance with the Research Criteria and in accordance with an IRB-approved research protocol. A dual liver-kidney transplant with from donors with HIV is not required to be conducted in accordance with the Research Criteria, as neither liver transplants nor kidney transplants from donors with HIV are required to be conducted as research.

Category	Previous Criteria	Revised Criteria [No longer pertains to kidney and liver transplants[1]]
	• No evidence of invasive opportunistic complications of HIV infection	deceased donor eligibility criteria should be followed. Other Organs: If a living donor with HIV donates another type or organ (other than kidney and liver), the deceased donor eligibility criteria should be followed.*
	Pre-implant donor organ biopsy	
Recipient Eligibility	CD4+ T-cell count ≥200/μL (kidney)	CD4+ T-cell count: no minimum threshold when all other recipient eligibility criteria are met.*
	CD4+ T-cell count ≥100 μL (liver) within 16 weeks prior to transplant and no history of opportunistic infection (OI); or ≥200 μL if history of OI is present.	
	HIV-1 RNA <50 copies/mL and on a stable antiretroviral regimen.	HIV-1 RNA <50 copies/mL and on a stable antiretroviral regimen.
	No evidence of active opportunistic complications of HIV infection.	No evidence of active opportunistic complications of HIV infection.
	No history of primary central nervous system (CNS) lymphoma or progressive multifocal leukoencephalopathy (PML).	No history of primary central nervous system (CNS) lymphoma or progressive multifocal leukoencephalopathy (PML).
Transplant Hospital Criteria	Transplant hospital with established program for care of subjects with HIV.	Transplant hospital with established program for care of patients with HIV.
	HIV program expertise on the transplant team.	HIV program expertise on the transplant team.
	Organ-specific experience with transplants of organs from donors without HIV to recipients with HIV (5 D-/R+ transplant cases over 4 years).	There is no longer a center specific case experience requirement with transplants of organs from donors without HIV to recipients with HIV.* Transplant patients with organs from donors with HIV must be managed with a multidisciplinary team before, during, and after transplant. The multidisciplinary team must include transplant surgeons, physicians, HIV specialists, nurses, social workers, and pharmacists capable of therapeutic drug monitoring to minimize drug-drug interactions.
	Standard operating procedures (SOPs) and training for the organ procurement, implanting/operative, and postoperative care teams for handling subjects with HIV, and organs and tissues from individuals with HIV.	Standard operating procedures (SOPs) and training for the organ procurement, implanting/operative, and postoperative care teams for handling HIV-infected subjects with HIV, and organs and tissues from individuals with HIV.

Category	Previous Criteria	Revised Criteria [No longer pertains to kidney and liver transplants[1]]
	IRB-approved research protocol for transplantation of organs from donors with HIV in recipients with HIV.	IRB-approved research protocol for transplantation of organs from donors with HIV in recipients with HIV for the applicable organs.*
	Institutional biohazard plan outlining measures to prevent and manage inadvertent exposure to and/or transmission of HIV.	Institutional biohazard plan outlining measures to prevent and manage inadvertent exposure to and/or transmission of HIV.
	Provide each living donor with HIV and recipient with HIV with an "independent advocate".	There is no longer a requirement to provide an HIV independent advocate beyond standard site practices.*
	Policies and SOPs governing the necessary knowledge, experience, skills, and training for independent advocates.	Policies and SOPs governing the necessary knowledge, experience, skills, and training for independent advocates.
OPO Responsibilities	SOPs and staff training procedures for working with deceased donors with HIV and their families in pertinent history taking; medical chart abstraction; the consent process; and handling blood, tissues, organs, and biospecimens.	SOPs and staff training procedures for working with deceased donors with HIV and their families in pertinent history taking; medical chart abstraction; the consent process; and handling blood, tissues, organs, and biospecimens.
	Biohazard plan to prevent and manage HIV exposure and/or transmission.	Biohazard plan to prevent and manage HIV exposure and/or transmission.
Prevention of Inadvertent Transmission of HIV	Each participating Transplant Program and OPO shall develop an institutional biohazard plan for handling organs from HIV-positive donors that is designed to prevent and/or manage inadvertent transmission or exposure to HIV.	Each participating Transplant Program and OPO shall develop an institutional biohazard plan for handling organs from HIV-positive donors that is designed to prevent and/or manage inadvertent transmission or exposure to HIV.
	Procedures must be in place to ensure that human cells, tissues, and cellular and tissue-based products (HCT/Ps) are not recovered from donors with HIV for implantation, transplantation, infusion, or transfer into a human recipient; however, HCT/Ps from a donor determined to be ineligible may be made available for nonclinical purposes.	Procedures must be in place to ensure that human cells, tissues, and cellular and tissue-based products (HCT/Ps) are not recovered from donors with HIV for implantation, transplantation, infusion, or transfer into a human recipient; however, HCT/Ps from a donor determined to be ineligible may be made available for nonclinical purposes.
Required Data Elements and Outcome Measures**		
Wait List Candidates	HIV status	HIV status
	CD4+ T-cell counts	CD4+ T-cell counts

Category	Previous Criteria	Revised Criteria [No longer pertains to kidney and liver transplants[1]]
	Co-infection (hepatitis C virus [HCV], hepatitis B virus [HBV])	Co-infection: • Hepatitis C (HCV RNA) • Hepatitis B (HBV deoxyribonucleic acid, HBV antibody) • Cytomegalovirus (CMV immunoglobulin G [IgG])*
	HIV viral load	HIV viral load
	ART resistance	ART resistance
	Removal from wait list (death or other reason) Time on wait list	Removal from wait list (death or other reason) Time on wait list Renal dysfunction* Liver dysfunction* Indication for transplant* Use of mechanical circulatory devices* Use of extracorporeal membrane oxygenation, intra-aortic balloon pump, ventricular assist device*
Donors (all)	Type (Living or deceased)	Type Donation after Brain Death vs. Donation after Circulatory Death vs. Living Donor*
	HIV status (new diagnosis of HIV, or known diagnosis of HIV)	HIV status (new diagnosis of HIV, or known diagnosis of HIV)
	CD4+ T-cell count	CD4+ T-cell count
	Co-infection (HCV, HBV)	Co-infection (HCV, HBV)
	HIV viral load	HIV viral load
	ART resistance	ART resistance
		Ex-vivo perfusion* • Duration • Warm and cold ischemia time Normothermic regional perfusion* • Duration • Warm and cold ischemia time
Living Donors	Progression to renal insufficiency in kidney donors	These data elements no longer apply since kidney or liver donation from a living donor with HIV no longer falls under the Research Criteria except that these data elements apply to simultaneous multiple organ transplants.
	Progression to hepatic insufficiency in liver donors	
	Change in ART regimen as a result of organ dysfunction	Change in ART regimen as a result of organ dysfunction
	Progression to acquired immunodeficiency syndrome (AIDS)	Progression to AIDS

Category	Previous Criteria	Revised Criteria [No longer pertains to kidney and liver transplants[1]]
	Failure to suppress viral replication (persistent HIV viremia)	Failure to suppress viral replication (persistent HIV viremia)
	Death	Death
Transplant Recipients	Rejection rate (annual up to 5 years)	Rejection rate (annual through 5 years)
	Progression to AIDS	Progression to AIDS
	New OI	New OI
	Failure to suppress viral replication (persistent HIV viremia)	Failure to suppress viral replication (persistent HIV viremia)
	HIV-associated organ failure	HIV-associated organ failure
	Malignancy	Malignancy
	Graft failure	Graft failure
	Mismatched ART resistance versus donor	Mismatched ART resistance versus donor
	Death	Death
		Type of rejection (antibody mediated versus cellular rejection) *
		Chronic heart allograft vasculopathy*
		Chronic lung allograft dysfunction*
		Hospitalized infections*
		Estimated glomerular filtration rate*
		HIV superinfection*
		Re-transplantation*
		Simultaneous multiple organ transplants

*Denotes a revision of the 2015 Research Criteria

**The previous category of outcome measures (from the original 2015 Research Criteria) is modified to also include data elements.

A summary of the revisions in each category of the Research Criteria is provided below as compared with the 2015 Research Criteria.

Donor Eligibility:

The only change to this category applies to all deceased donors with HIV. NIH has removed the requirement for a pre-implantation donor organ biopsy. Although pre-implantation biopsies for kidneys and livers have occurred regularly, pre-implant donor heart and lung biopsies are not routinely performed. Likewise, donor biopsies for other organs are not routine. Given that kidney and liver transplants are no longer subject to the Research Criteria, NIH has removed the

requirement for pre-implantation biopsies. Any pre-implant biopsies obtained, as part of future IRB-approved research protocols, should be stored in accordance with local institutional requirements and the federal regulations applicable to slides, tissues and blocks, if applicable. 42 CFR 493.1105 (*https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-J/section-493.1105*).

With respect to living donors with HIV, the 2015 Research Criteria defined a well-controlled HIV infection and required pre-implant donor organ biopsies. The last living lobar lung transplant procedure in the U.S. was performed in 2013. NIH has removed this element as not relevant for heart and lung transplantation except in the rare instances of living donor lung transplant or "domino" heart transplants. In such circumstances, the deceased donor eligibility criteria apply. If another type of organ is donated by a living donor with HIV, the deceased donor eligibility criteria apply.

Recipient Eligibility:

The only change in this category concerns CD4+ T-cell counts. The 2015 Research Criteria imposed requirements with respect to the CD4+ T-cell counts specific to livers and kidneys. Given that kidney and liver transplants are no longer required to comply with the Research Criteria, there is no minimum threshold CD4+ T-cell counts for other organs when all other eligibility criteria are met.

Transplant Hospital:

NIH made several changes to this category. The requirement for prior experience with transplantation of organs from donors without HIV in recipients with HIV. The 2015 Research Criteria required experience with five transplants over the four preceding years involving organs from donors without HIV transplanted into recipients with HIV. NIH has removed this requirement, which was perceived by many as burdensome and a barrier to entry to transplant hospitals wishing to perform HOPE Act transplants. To maximize favorable outcomes and effectively prevent and manage adverse events, NIH has specified that all patients with

transplants involving donors with HIV be managed by multidisciplinary teams before, during, and after transplantation. NIH outlines specific members of this multidisciplinary team.

NIH has removed the requirement that each living donor with HIV and each transplant recipient with HIV be provided with an HIV independent advocate. NIH advises that standard site practices apply. Based on a decade of HOPE Act clinical experience, stakeholder surveys have indicated that a requirement for an independent advocate is widely perceived as a redundant layer of consent and a potential barrier for some HIV patients who would otherwise benefit from an HIV donor transplant. The NIH notes that per current OPTN policy and guidance, all living donors, including those with HIV, have an independent advocate. NIH's change to the 2015 Research Criteria will not alter that.

Organ Procurement Organization (OPO) Responsibilities:

NIH did not make any changes to this category.

Prevention of Inadvertent Transmission of HIV:

NIH did not make any changes to this category.

Required Outcome Measures and Data Elements:

The 2015 Research Criteria referenced required outcome measures. NIH is using the more precise "Required Data Elements and Outcome Measures." NIH notes that data on these existing and new outcome measures is collected by the OPTN as specified by the Secretary. NIH does not intend to incorporate data collection requirements beyond those collected by the OPTN.

Waitlist Candidates: NIH has added several data elements for waitlist candidates. NIH has added cytomegalovirus (CMV immunoglobulin G [IgG]) as a required outcome measure for co-infection. NIH also included the following additional data elements and outcome measures: renal dysfunction, liver dysfunction, indication for transplant, use of mechanical circulatory devices, and use of extracorporeal membrane oxygenation, intra-aortic balloon pump, and ventricular assist device.

Donors (All): First, NIH included additional elements related to type of deceased donation: after brain death (DBD) or after circulatory death (DCD) given the increasing use of the latter technique in the U.S. In addition, NIH has added the following data elements for all donors (if applicable): *ex-vivo* perfusion and normothermic regional perfusion including durations of warm and cold ischemia.

Living Donors: The 2015 Research Criteria included as required outcome measures progression to renal insufficiency in kidney living donors. Because kidney and liver transplants are no longer subject to the Research Criteria, NIH plans to retain these outcomes only where applicable (e.g., for deceased donor heart-living donor kidney transplants, deceased donor heart-living donor liver transplants, and for other organs subject to the Research Criteria).

Transplant Recipients: NIH has added several additional data elements and outcome measures to those included for transplant recipients in the 2015 Research Criteria. NIH has added the following outcome measures: type of rejection (antibody mediated versus cellular rejection), chronic allograft vasculopathy (heart), chronic lung allograft dysfunction (lung), hospital infections, estimated glomerular filtration rate (heart and lung), HIV superinfection, graft failure (heart and lung), re-transplantation, and simultaneous multiple organ transplants. While not included as a requirement of the Research Criteria, NIH has included the following recommendation regarding patient management:

NIH recommends that transplant programs and healthcare providers follow current and updated practice management guidelines. For specific guidance, transplant programs and healthcare providers should consult vaccination guidance (*https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html*) and expert guidance for the management of patients with HIV pre-, during-, and post-transplant summarized in: Transplantation in people with HIV (*https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new*).

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Principal Deputy Director,

National Institutes of Health.

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