providing conference, meeting, or seminars services are required to provide specific information to HHS as stated in the HHS Acquisition Regulation.

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
	Business (Contractor)	1,067	1	1	1,067
Total		1,067	1	1	1,067

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–27806 Filed 11–26–24; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be held as a virtual meeting and open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/watch=55419.*

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: January 14, 2025.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: NHLBI Sickle Cell Disease Program Updates and Long Term Follow-up of Participants undergoing gene therapy for SCD.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: julie.panepinto@nih.gov.

Meeting Format: Virtual Meeting.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/advisory-and-peer-review-committees/nhlbi-sickle-cell-disease-advisory-committee* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 22, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27878 Filed 11–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

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

ACTION: Request for comments.

SUMMARY: The HOPE Act requires the Secretary of Health and Human Services (the Secretary) to develop and publish criteria for research involving the transplantation of organs from donors with HIV to recipients with HIV. In 2015, the National Institutes of Health (NIH), and the U.S. Department of Health and Human Services (HHS) published research criteria applicable to such transplants, which have been in effect for all transplants involving organs from donors with HIV as authorized by the HOPE Act. As amended in an HHS final rule published elsewhere in this issue of the **Federal Register**, the Secretary determined 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 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 research criteria. Given this regulatory change, NIH proposes to delete aspects of the research criteria that are specific to kidney and liver transplantation. NIH proposes additional 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. NIH invites the public to submit comments regarding the proposed changes to the research criteria.

DATES: To ensure that comments will be considered, comments must be received no later than 5 p.m. on December 12, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Email: HOPEAct@mail.nih.gov.*
- *Fax:* 301–451–5671.
- *Regular Mail:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Bethesda, MD 20892–9827.
- *Hand Delivery, Overnight Mail, FedEx, and UPS:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Jonah Odim, Chief Clinical Transplantation Section, Transplantation Branch, 5601 Fishers

Lane, Room 6B21, MSC 9827, Rockville, MD 20892–9827; by email at *odimj@niaid.nih.gov;* by telephone at (301) 828–7220.

SUPPLEMENTARY INFORMATION:

I. 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.

1. Proposed Changes to the 2015 Research Criteria

NIH is now proposing 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 proposes to remove requirements from the Research Criteria applicable to HOPE Act kidney and liver transplants.

NIH also proposes 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. The proposed 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.

2. Consideration of Public Comment Received on the HOPE Act NPRM

In proposing these changes, NIH has considered the public participation in the HOPE Act rulemaking process through which the Secretary's determination was made. In response to the September 21, 2024, notice of proposed rulemaking that proposed the Secretary's determination with respect to HOPE Act kidney and liver transplants, 89 FR 74174, HHS received multiple comments that were relevant to the NIH Research Criteria, and some comments provided specific suggestions for the content of the revised NIH Research Criteria. All comments relating to the content of the revised Research Criteria were provided to NIH for consideration in the development of the proposed revised Research Criteria that appear later in this document. NIH has considered these comments and proposes changes to the Research Criteria responsive to specific comments received, as described here.

- Several commenters noted that referring to organs ''infected with HIV'' or ''HIV positive organs'' may be stigmatizing, and one commenter requested that references to ''organs with HIV'' be revised to ''organ(s) from donors with HIV.'' The commenters indicated a strong preference for the use of stigma-reducing, and person-first language. In response to these comments, NIH proposes to revise references in the Research Criteria to refer to donors with HIV, recipients with HIV, and organs from donors with HIV. This is consistent with the Centers for Disease Control and Prevention's (CDC) Stigma Language Guide [1] and with language adopted in the final rule.
- Commenters also requested the elimination of the current requirement that a transplant team perform at least five transplants within a four-year period between any donor and a recipient with HIV for all organs, as, in the commenters' estimation, this

[1] Centers for Disease Control and Prevention. Let's Stop HIV Together: Stigma Language Guide. *https://www.cdc.gov/stophivtogether/hiv-stigma/ways-to-stop.html.* Accessed 2/23/2024.

requirement is not necessary for organs from donors with HIV to be used safely. In response to these comments and based on its review of the evidence, NIH proposes to remove this requirement from the proposed revised Research Criteria.

- Commenters suggested that each transplant team should include infectious disease specialists with expertise in HIV care. In response to these comments and based on its review of the evidence, NIH proposes that this requirement of the 2015 NIH Research Criteria be retained in the revised Research Criteria.
- One commenter requested the elimination of the biopsy requirement. In response to this comment and based on its review of the evidence, NIH proposes to eliminate the requirement for a pre-implantation biopsy.
- One commenter noted that, in revising the Research Criteria, NIH should maintain the strong patient safety record for HOPE Act transplants, while actively seeking to reduce burdens that may be slowing the establishment of non-kidney and non-liver HOPE Act transplant programs. In response to this comment and based on its review of the evidence, NIH believes that the proposed revisions to the Research Criteria appropriately strike this balance.

NIH's rationale for these specific proposed revisions to the Research Criteria is provided in more detail in Section III, below.

The Secretary delegated to the Director, NIH, the responsibility to revise the 2015 Research Criteria. The proposed revised Research Criteria proposed below were developed by NIH staff in collaboration with representatives of the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, and the Office of the Assistant Secretary for Health.

If adopted as proposed, it is anticipated that the revised Research Criteria would expand access to transplantation for recipients with HIV, provide benefits to organ donors; ensure safety of ongoing HOPE Act transplants of organs other than kidneys and livers; and provide for the systematic collection of safety and efficacy data related to transplants of hearts, lungs, and other organs from donors with HIV in recipients with HIV.

3. Other Considerations

(a) Research Results—Heart and Lung Transplants in Recipients With HIV

As the Secretary has decided that HOPE Act transplants of organs other than kidneys and livers should remain subject to the Research Criteria until additional scientific research demonstrates the safety and efficacy of such transplants, NIH wishes to highlight the current state of the science with regard to transplantation of hearts and lungs from donors without HIV in recipients with HIV. The early outcomes data for such transplants may provide a foundation for future HOPE Act thoracic organ transplants (Koval 2018, 2019; Madan 2019). For example, in a retrospective analysis utilizing the OPTN database to compare outcomes of 75 heart transplant recipients with HIV to those of 29,848 heart transplant recipients without HIV, survival rates were similar across the comparator groups, while rejection rates were approximately 2-fold higher in recipients with HIV (38.7% vs. 17.7%, respectively) (Doberne 2021). Similar findings were reported in studies based on the International Society for Heart and Lung Transplantation (ISHLT) and Scientific Registry of Transplant Recipients (SRTR) databases (Wairmu 2021; Storm 2024; Madan 2019). Fewer transplants of lungs from donors without HIV in recipients with HIV have been reported (Koval 2019; Kern 2014; Rouzaud 2022).

NIH recognizes that additional research in this area will advance the state of the relevant science, and the results of such research will increase the evidence basis needed to support any future determination by the Secretary that participation in clinical research is no longer a requirement for transplants of hearts or lungs from donors with HIV in recipients with HIV.

(b) Education Regarding the HOPE Act

While no related proposals are included in the proposed revision to the 2015 Research Criteria, NIH further notes that expanding awareness and continuing education of potential organ donors, transplant centers, organ procurement organizations (OPOs), healthcare providers, and people living with HIV will be important to fully realize the medical and societal benefits envisioned under the HOPE Act. Success in these endeavors will expand the supply of quality donor HIV organs, enhance transplant access, improve quality of life, and increase longevity for potential transplant recipients with HIV. Reducing longstanding stigma and increasing access to organ transplantation will be particularly important for communities disproportionately impacted by HIV (*https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/who-is-at-risk-for-hiv*).

(D) Secretary's Review of Research Results

As stated above, the HOPE Act requires that the Secretary, in conjunction with the OPTN, periodically review the results of scientific research to determine whether the results warrant revision to the OPTN standards of quality with respect to organs from donors with HIV and the safety of transplanting an organ from a donor with a particular strain of HIV into a recipient with a different strain of HIV. 42 U.S.C. 274f–5(c)(1). This review allows the Secretary to determine if the safety and efficacy of HOPE Act transplants are comparable to non-HOPE Act transplants and, if warranted, to further determine whether such transplants may be conducted outside of a research setting.

Past procedures for this review are described in detail in the final rule amending the OPTN regulation. Past reviews involved deliberations by bodies that provided recommendations to the Secretary, including the OPTN (which solicited and considered public comments)[2] [3] the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)[4] and the HHS Blood, Organ, and Tissue Senior Executive Council (BOTSEC) (an advisory forum for senior leadership from HHS entities involved in blood, organ, and tissue safety and availability. The recommendations of the OPTN, ASBTSA, and BOTSEC, as well as subsequent research results, were considered in the Secretary's decision as to whether participation in clinical research, as a requirement for certain types of transplants of organs from donors with HIV, is no longer warranted.

Although not incorporated into the 2015 Research Criteria or the proposed revised criteria, HHS intends to conduct a regular review of such scientific research to enable evidence-based recommendations, including any changes to the Research Criteria, and any determinations on transitioning additional HOPE Act organ transplants to medical practice and standard-of-care

[2] Organ Procurement and Transplantation Network. Public Comment Proposal: Modify the HOPE Act Variance to Include Other Organs. 2019 Jan 22: *https://optn.transplant.hrsa.gov/media/2800/dtac_publiccomment_20190122.pdf.*

[3] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

[4] HHS Advisory Committee on Blood and Tissue Safety and Availability. 2022. Fifty-Sixth ACBTSA Meeting November 17, 2022—Meeting Summary. *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meeting-summary/2022-11-17/index.html.*

(*i.e.,* removing the clinical research and IRB requirements for such transplants) if appropriate in the future. NIH seeks public comment on this approach, and on the procedures through which this review should be conducted.

II. Instructions for Submitting Comments

Comments are invited on the proposed changes to the 2015 Research Criteria.

Please note that, during the rulemaking process resulting in the HHS final rule published elsewhere in this issue of the **Federal Register**, HHS received and considered public comments regarding whether HOPE Act kidney and liver transplants from donors with HIV should continue to be required to be conducted in accordance with the 2015 Research Criteria. After consideration of public comments received, the Secretary determined that participation in clinical research will no longer be a requirement for HOPE Act kidney and liver transplants from donors with HIV.

Further, in making the determination regarding HOPE Act kidney and liver transplants, the Secretary expressed the view in the notice of proposed rulemaking published on September 12, 2024, 89 FR 74174, that the current research and IRB requirements should be maintained for HOPE Act transplants of all other organs, considering the lack of data on outcomes for HOPE Act organ transplants other than kidney or liver transplants. This decision was affirmed in the HHS final rule published elsewhere in this issue of the **Federal Register**.

Because the Secretary's determination regarding HOPE Act kidney and liver transplants, and the Secretary's decision that other HOPE Act organ transplants should remain subject to the Research Criteria, resulted from full notice and comment rulemaking procedures, NIH views comments concerning the Secretary's determination or decision to be outside the scope of this solicitation and such comments will not be considered. Specifically, related comments will not be considered with respect to these proposed changes to the 2015 Research Criteria: (1) eliminating the requirement that transplants involving kidneys and livers from donors with HIV comply with the NIH Research Criteria; (2) retaining the requirement that transplants involving all other organs (other than kidneys and livers) from donors with HIV comply with the NIH Research Criteria; and (3) removal of criteria specific to the transplantation of kidneys and livers.

Do not include personal information in submitted comments that you do not want to be publicly disclosed.

III. Proposed Revision to the 2015 Research Criteria

The proposed revision to the 2015 Research Criteria is as follows:

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

Table of Contents

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 the time of publication of this research criteria document.

The 2015 Research Criteria are outlined 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 proposed new HOPE Act Research Criteria in each category

and compares them to the 2015 NIH Research Criteria.

TABLE 1—PROPOSED 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	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
Donor Eligibility:		
All deceased donors with HIV	No evidence of invasive opportunistic complications of HIV infection.	No evidence of invasive opportunistic complications of HIV infection.
	Pre-implant donor organ biopsy	There is no requirement for a pre-implantation biopsy.*
	Viral load: no requirement	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 • No evidence of invasive opportunistic complications of HIV infection	*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 deceased donor eligibility criteria should be followed.
	Pre-implant donor organ biopsy	*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.*
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.
	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.

TABLE 1—PROPOSED REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV [1]—Continued

Category	Previous criteria	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
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 non-clinical 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 non-clinical purposes.
Required Data Elements and Outcome Measures **		
Wait List Candidates	HIV status	HIV status.
	CD4+ T-cell counts	CD4+ T-cell counts.
	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)	Removal from wait list (death or other reason).
	Time on wait list	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 Progression to hepatic insufficiency in liver 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.
	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.
	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.

TABLE 1—PROPOSED REVISED HUMAN IMMUNODEFICIENCY VIRUS (HIV) ORGAN POLICY EQUITY (HOPE) ACT SAFEGUARDS AND RESEARCH CRITERIA FOR TRANSPLANTATION OF ORGANS FROM DONORS WITH HIV [1]—Continued

Category	Previous criteria	Proposed revised criteria (No longer pertains to kidney and liver transplants [5])
	New OI Failure to suppress viral replication (persistent HIV viremia). HIV-associated organ failure Malignancy Graft failure Mismatched ART resistance versus donor Death	New OI. Failure to suppress viral replication (persistent HIV viremia). HIV-associated organ failure. Malignancy. Graft failure. Mismatched ART resistance versus donor. 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 proposed revisions in each category of the Research Criteria is provided below.

Donor Eligibility

The only change proposed by NIH to this category applies to all deceased donors with HIV. NIH proposes removing 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 NIH research criteria, NIH proposes removing 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 NIH 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 proposes removing 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, NIH proposes that the deceased donor eligibility criteria apply. If another type of organ is donated by a living donor with HIV, NIH proposes that the deceased donor eligibility criteria apply.

Recipient Eligibility

The only change proposed in this category concerns CD4+ T-cell counts. The 2015 NIH 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, NIH proposes no minimum threshold CD4+ T-cell counts for other organs when all other eligibility criteria are met.

Transplant Hospital

NIH proposes several changes to this category. The requirement for prior experience with transplantation of organs from donors without HIV in recipients with HIV. The 2015 NIH Research Criteria required experience with five transplants over the four preceding years involving organs from donors without HIV transplanted into recipients with HIV. NIH proposes removing 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 proposes that all patients with transplants involving donors with HIV be managed by multidisciplinary teams before, during, and after transplantation. NIH proposes specific members of this multidisciplinary team.

NIH proposes removing the requirement that each living donor with HIV and each transplant recipient with HIV be provided with an HIV-independent advocate. NIH proposes instead 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 proposed change to the 2015 Research Criteria will not alter that.

[5] 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.

Organ Procurement Organization (OPO) Responsibilities

NIH does not propose changes to this category.

Prevention of Inadvertent Transmission of HIV

NIH does not propose changes to this category.

Required Outcome Measures and Data Elements

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

Waitlist Candidates: NIH proposes adding several data elements for waitlist candidates. NIH proposes adding cytomegalovirus (CMV immunoglobulin G [IgG]) as a required outcome measure for co-infection. NIH also proposes adding 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 proposes adding additional elements related to the 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 proposes 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 NIH 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 proposes adding several additional data elements and outcome measures to those included for transplant recipients in the 2015 NIH Research Criteria. NIH proposes adding 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 proposed as a requirement of the Research Criteria, NIH proposes to provide 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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Dated: November 21, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE).

Date: January 16, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240–276–6343, *schweinfestcw@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Informatics Technologies for Cancer Research.

Date: January 29, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.