OPTN

Briefing to the OPTN Board of Directors on

Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates

OPTN Ad Hoc Disease Transmission Advisory Committee

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OPTN

Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates

Affected Policies:	*1.2: Definitions* *2.7: HIV Screening of Potential Deceased Donors* *2.7.A: Exceptions to HIV Screening Requirement* *5.3.B: Infectious Disease Screening Criteria* *5.3.D: Liver Acceptance Criteria* *5.3.H: Kidney Offer Filters* *5.4.E: Allocation to Candidates Not on the Match Run* *5.5.C: OPO Requirements for Positive HIV Results* *5.8.A: Pre-Transplant Verification Prior to Organ Receipt* *5.8.B: Pre-Transplant Verification Upon Organ Receipt* *14.3: Informed Consent Requirements* *14.4.E: Living Donor Exclusion Criteria* *15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements* *15.3.B: Donors with Risk Identified Pre-Transplant* *15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* *15.7.A: Requirements for Allocating HIV Positive Deceased Donor Organs* *15.7.B: Requirements for Allocating HIV Positive Living Donor Organs* *15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs* *16.6.A: Extra Vessels Use and Sharing*
Sponsoring Committee:	*Ad Hoc Disease Transmission Advisory*
Public Comment Period:	*March 21 – April 22, 2025*
Board of Directors Meeting:	*June 9, 2025*

Executive Summary

The Ad Hoc Disease Transmission Advisory Committee (DTAC) proposes aligning OPTN policy with the recently amended OPTN Final Rule and National Institutes of Health (NIH) Final Notice regarding the transplants of kidneys, livers, and liver-kidneys from donors with HIV (human immunodeficiency virus) to recipients living with HIV.[1,2] As these transplants are no longer required to be conducted pursuant to a research protocol, they are not required to be conducted under the OPTN HOPE Act variance, but must meet additional patient safety requirements affirming candidate status and willingness to accept an organ from a donor with HIV at different timepoints prior to a transplant of an organ with HIV

[1] Health and Human Services Department, "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act", 89 FR 93484 (11/27/2024).
[2] 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", 89 FR 106542 (12/30/24).

occurring. Policy is also updated to differentiate between variance requirements that apply to non-kidney and non-liver organs, and requirements for kidneys, livers, and liver-kidneys. Language throughout policy is updated to appropriately refer to individuals with HIV, in alignment with the amended OPTN Final Rule.

The proposal was available for feedback during a special public comment cycle to support an accelerated timeline for aligning OPTN policy to the amended OPTN Final Rule and NIH Final Notice.[3] During public comment, the proposal received widespread support from almost every stakeholder organization, committee, patient, and OPTN member that participated. The support extended to both the alignment with federal changes as well as the additional patient safety measures. One stakeholder organization (the American Society of Transplantation or AST) and one OPTN committee (the Living Donor Committee) identified special considerations that the DTAC should consider regarding long-term health of living donors who donate while living with HIV. In response, DTAC added a required element of informed consent for these donors to *Policy 14.3: Informed Consent Requirements*.

After the public comment period, staff identified additional questions regarding the implementation of the proposed changes aligning with the amended OPTN Final Rule for the OPTN kidney paired donation (KPD) program. Historically, the OPTN KPD program was not intended to be included in the OPTN HOPE Act variance.[4] It was identified that several aspects of *Policy 13: Kidney Paired Donation (KPD)* would have to be modified to safely allow for paired donation between individuals with HIV. The DTAC considers it important to not limit access to candidates, in alignment with the amended OPTN Final Rule. However, the DTAC has consistently sought to maintain patient safety throughout the process by which access is expanded. The DTAC considers additional consideration by the OPTN Kidney Committee or OPTN KPD Workgroup is required to safely pursue paired HIV transplants. DTAC clarified that the proposed changes in *Policy 15.7.B: Transplant Program Requirements for Transplantation of Organs from Donors with HIV* apply only to deceased donor match runs, so no OPTN policy allows KPD transplants for pairs of individuals with HIV. DTAC did not further modify the proposal, given the extent of the complexity of the KPD changes that warrant careful consideration because of patient safety.

The 2013 federal HOPE Act allows organ transplantation from donors with HIV to candidates living with HIV at transplant programs that meet and follow research criteria guidelines published by the Department of Health and Human Services (HHS) through the NIH.[5,6] Since then, the HOPE Act has been demonstrated to be a successful effort to safely improve access to transplant for a vulnerable population. The proposed changes maintain patient safety as access expands so that more individuals living with HIV are able to obtain an organ transplant.

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[3] On November 27th, 2024, the U.S. Department of Health and Human Services (HHS) amended the OPTN Final Rule to remove research requirements for transplantation of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV. On December 30th, 2024, the NIH Final Notice modified research criteria for non-kidney and non-liver organs from donors with HIV to recipients living with HIV. The Health Resources and Services Administration (HRSA), an agency of HHS, provides oversight as to the OPTN. On January 7, 2025, HRSA directed on behalf of the HHS Secretary that changes be implemented in OPTN policy to align with the amended OPTN Final Rule and the NIH Final Notice on an accelerated timeline.

[4] *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act*, OPTN Organ Procurement Organization Committee, January 2015, https://optn.transplant.hrsa.gov/media/1147/0115_04_opo_hope_act.pdf (accessed May 7, 2025).

[5] 42 U.S.C. § 274(b)(3).

[6] National Institutes of Health, "Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV", 80 FR 73785 (11/25/2015).

Purpose

At the end of 2024, HHS published a Final Rule that requires changes to current OPTN policy regarding transplants for individuals living with HIV. HHS amended the OPTN Final Rule to remove research requirements for transplantation of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV.[7] A month later, NIH issued a Final Notice that modified the requirements for transplanting non-kidney and non-liver organs from donors with HIV to recipients living with HIV; these modifications included removing the requirement that the transplant program perform five HIV donor negative to HIV recipient positive transplants over four years.[8]

The purpose of this proposal is to align OPTN policy and system changes to comply with the amended OPTN Final Rule and NIH Final Notice so that

- Transplants of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV no longer require compliance with NIH research criteria or participation in an OPTN variance;
- Transplants of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV include adequate patient safety measures;
- Non-kidney and non-liver transplants of organs from donors with HIV to recipients with HIV still are required to be conducted in compliance with current NIH research criteria and through participation in the OPTN HOPE Act variance;
- Informed consent requirements for living kidney and liver donors with HIV are updated;
- Language is updated throughout to refer respectfully and consistently to individuals with HIV; and
- All existing and updated requirements are both clearly articulated and support patient safety.

An overarching goal is to ensure that patient safety is maintained as access to transplant for individuals with HIV is expanded. In accordance with living donor safety, a post-public comment change was made to require disclosure to living kidney and liver donors with HIV regarding the lack of data on long-term outcomes for individuals donating while living with HIV.

This proposal reflects a decade of efforts to expand access to individuals living with HIV, as detailed in the following section, "History of the HOPE Act Research Variance."

Background

History of the HOPE Act Research Variance

The HIV Organ Policy Equity (HOPE) Act, enacted November 2013, allowed for research to be conducted on the transplantation of organs from donors with HIV to recipients living with HIV at programs participating in an Institutional Review Board (IRB)-approved research protocol and in accordance with

[7] Health and Human Services Department, "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act", 89 FR 93484 (11/27/2024).
[8] 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", 89 FR 106542 (12/30/24).

NIH research criteria.[9] This ended a prohibition in the United States of the transplant of organs from donors with HIV. The effort to increase access for candidates living with HIV has been successful, as there have been over 500 successful transplants of organs from donors with HIV to recipients living with HIV and zero patient safety events.[10]

The initial OPTN HOPE Act variance applied only to livers and kidneys and was implemented in 2015.[11] As data accumulated and safety was maintained, the OPTN submitted policy changes to extend the HOPE Act variance to other organs.[12] The initial variance, as well as the substantive change to the variance expanding it to HOPE Act transplants of all organs, were adopted following supportive public comment.[13,14] Since 2013, the OPTN Board has approved three extensions of the variance expiration (see Table 1, below).[15,16,17] By 2021, the OPTN recommended removal of the requirement that HOPE Act transplants comply with NIH research criteria for all organs, citing the successful number of transplants and absence of safety issues.[18,19]

There are currently 58 participating transplant programs in the research variance, and among them there are 26 approved programs for deceased donor kidney, 16 programs for deceased donor liver, five programs for living donor kidney, and two programs for living donor liver.[20] There are currently four heart programs, two lung programs, and two heart-lung programs approved for participation in the OPTN variance.

More details on the federal and OPTN actions related to the HOPE Act research variance and allowing organ transplantation from donors with HIV to recipients living with HIV can be found in Table 1 on the next page.

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[9] HIV Organ Policy Equity Act, Pub. L. No. 113-51 (11/21/2013).

[10] OPTN data as of January 10, 2025.

[11] *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act*, OPTN Organ Procurement Organization Committee, January 2015, https://optn.transplant.hrsa.gov/media/1147/0115_04_opo_hope_act.pdf (accessed May 7, 2025).

[12] *Modify HOPE Act Variance to Include Other Organs*, OPTN Ad Hoc Disease Transmission Advisory Committee, June 2019, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-hope-act-variance-to-include-other-organs/#:~:text=In%20November%202015%2C%20OPTN/UNOS,participation%20criteria%20in%20November%202015 (Accessed May 7, 2025).

[13] *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act*, OPTN Organ Procurement Organization Committee, January 2015, https://optn.transplant.hrsa.gov/media/1147/0115_04_opo_hope_act.pdf (accessed May 7, 2025).

[14] *Modify HOPE Act Variance to Include Other Organs*, OPTN Ad Hoc Disease Transmission Advisory Committee, June 2019, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-hope-act-variance-to-include-other-organs/#:~:text=In%20November%202015%2C%20OPTN/UNOS,participation%20criteria%20in%20November%202015 (Accessed May 7, 2025).

[15] *Change to the HOPE Act Variance Expiration Date*, OPTN Organ Procurement Organization Committee, December 2017. https://optn.transplant.hrsa.gov/media/2334/opo_boardreport_201712.pdf (Accessed May 7, 2025).

[16] *Change Expiration Date of HOPE Act Variance*. OPTN Ad Hoc Disease Transmission Advisory Committee, December 2019, https://optn.transplant.hrsa.gov/media/3454/hope-act-policy-notice-mini-brief.pdf (Accessed May 7, 2025).

[17] *Extend HIV Organ Policy Equity (HOPE) Act Variance*, OPTN Ad Hoc Disease Transmission Advisory Committee, December 2021, https://optn.transplant.hrsa.gov/media/t1sdej22/policy-notice_dtac_hope_variance.pdf (Accessed May 7, 2025).

[18] Matthew Cooper. OPTN Letter to Secretary Becerra on the HOPE Act, October 29, 2021, *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf* (Accessed May 7, 2025).

[19] OPTN Descriptive Data Request. "One Year Evaluation of the Modification of OPTN HOPE Act Variance to Include Other Organ." Prepared for the OPTN Ad Hoc Disease Transmission Advisory Committee Conference Call, July 28, 2021.

[20] Upon Board approval and policy implementation, kidney, liver, and liver-kidney programs will no longer be included as participants in the HOPE Act variance – this is in accordance with changes to OPTN Policy detailed in this proposal and the regulations outlined in the amended OPTN Final Rule.

Table 1: Federal and OPTN Actions Related to Allowing Transplantation of Organs from Donors with HIV to Recipients Living with HIV

Date	Action
11/2013	HIV Organ Policy Equity (HOPE) Act enacted as federal law[21]
9/2014-12/2014	First public comment period as a concept paper to develop OPTN requirements to allow transplantation of organs from donors with HIV to recipients living with HIV under the HOPE Act[22] • The concept paper received unanimous support from the community
1/2015-3/2015	Second public comment period to develop OPTN requirements to allow transplantation under the HOPE Act[23] • The proposal received unanimous support from the community
6/2015	Publication of draft NIH safeguards and research criteria for transplantation of organs from donors with HIV[24]
6/2015	OPTN Board approval to address requirements to allow transplantation under the HOPE Act[25] • Included establishment of an open policy variance, changes to infectious disease verification, organ and extra vessel label requirements, and acceptance, exclusion, and allocation criteria Implemented 11/19/2015
11/2015	Publication of the final NIH safeguards and research criteria for transplantation of organs from donors with HIV[26]
6/2016	OPTN Board approval to clarify data submission requirements for HOPE Act variance, establish variance expiration date of 1/1/2018[27]
12/2017	OPTN Board approval to change the HOPE Act variance expiration date from 1/1/2018 to 1/1/2020[28] • No change to existing variance or policies
1/2019-3/2019	Third public comment period to modify HOPE Act variance to include all organs[29] • The proposal received unanimous support from the community
6/2019	OPTN Board approval to modify HOPE Act variance to include all organs[30] • Implemented 5/21/2020[31]
12/2019	OPTN Board approval to change expiration date of HOPE Act variance from 1/1/2020 to 1/1/2022[32] • No change to existing variance, non-substantive clarification to policies
10/2021	OPTN Board recommended removal of the requirement to adhere to NIH research criteria for all HOPE Act organs in a letter to the Secretary[33]
12/2021	OPTN Board approval to change expiration date of HOPE Act variance from 1/1/2022 to 1/15/2026[34]
11/2022	Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) meets and recommends removing the NIH research criteria requirements for HOPE Act transplants of kidneys and livers[35]
11/2022	OPTN letter to the ACBTSA indicating support for removal of research criteria requirements for HOPE Act transplants of all organs[36]
11/2024	Amended OPTN Final Rule to remove research criteria requirements for HOPE Act kidney, liver, and liver-kidney transplants[37]
12/2024	Publication of NIH Final Notice to modify research criteria for HOPE Act non-kidney and non-liver organs[38]

Safety of HOPE Act Transplants

This proposal identifies measures to ensure that a successful record of patient safety is maintained as research protocol requirements are removed for the transplantation of kidney, liver, and liver-kidneys from donors with HIV to recipients living with HIV.

The amended OPTN Final Rule and subsequent changes to OPTN policies reflect the success of HOPE Act transplants in achieving patient safety. Over 500 patients living with HIV have received organ transplants under the OPTN HOPE Act policy variance.[39] There have been no patient safety concerns identified by any data safety monitoring board. No protocol has been halted, paused, or substantially amended to address recipient safety concerns. Within the well-established OPTN safety reporting structures, there have been no reports of safety issues related to HOPE Act transplantation among organ procurement organization, hospital, or transplant program personnel or in patients in donor hospitals or transplant hospitals.[40] There have been only three living donor transplants under the HOPE Act to date. Transplants by organ that have occurred under the OPTN HOPE Act Variance can be seen in Figure 1 below.

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[21] HIV Organ Policy Equity Act, Pub. L. No. 113-51 (11/21/2013).

[22] *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act*, OPTN Organ Procurement Organization Committee, September 2014.

[23] *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act*, OPTN Organ Procurement Organization Committee, January 2015, https://optn.transplant.hrsa.gov/media/1147/0115_04_opo_hope_act.pdf (accessed May 7, 2025).

[24] National Institutes of Health, "Draft Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV", 80 FR 34912-34921 (6/18/2015)

[25] *Addressing Requirements in the HIV Organ Policy Equity Act*, OPTN Board of Directors, June 2015.

[26] National Institutes of Health, "Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV", 80 FR 73785-73796 (11/25/2015).

[27] *Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*, OPTN Ad Hoc Disease Transmission Advisory Committee, June 2016, https://optn.transplant.hrsa.gov/media/1866/dtac_briefingpaper_hope_201606.pdf (Accessed May 7, 2025).

[28] *Change to the HOPE Act Variance Expiration Date*, OPTN Organ Procurement Organization Committee, December 2017. https://optn.transplant.hrsa.gov/media/2334/opo_boardreport_201712.pdf (Accessed May 7, 2025).

[29] *Modify HOPE Act Variance to Include Other Organs*, OPTN Ad Hoc Disease Transmission Advisory Committee, January 2019, https://optn.transplant.hrsa.gov/media/2800/dtac_publiccomment_20190122.pdf (Accessed May 7, 2025).

[30] *Modify HOPE Act Variance to Include Other Organs*, OPTN Board of Directors, June 2019, https://optn.transplant.hrsa.gov/media/3000/dtac_policynotice_201906.pdf (Accessed May 7, 2025).

[31] Ibid.

[32] *Change Expiration Date of HOPE Act Variance*. OPTN Ad Hoc Disease Transmission Advisory Committee, December 2019, https://optn.transplant.hrsa.gov/media/3454/hope-act-policy-notice-mini-brief.pdf (Accessed May 7, 2025).

[33] Matthew Cooper. OPTN Letter to Secretary Becerra on the HOPE Act, October 29, 2021, *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf* (Accessed May 7, 2025).

[34] *Extend HIV Organ Policy Equity (HOPE) Act Variance*, OPTN Board of Directors, December 2021, https://optn.transplant.hrsa.gov/media/t1sdej22/policy-notice_dtac_hope_variance.pdf (Accessed May 7, 2025).

[35] 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*.

[36] Jerry McCauley. Fifty Sixth ACBTSA Meeting, Written Public Comment—November 17, 2022 Meeting, November 8, 2022, *https://optn.transplant.hrsa.gov/media/hwgncda2/optn-executive-committee_acbtsa-letter.pdf* (Accessed May 7, 2025).

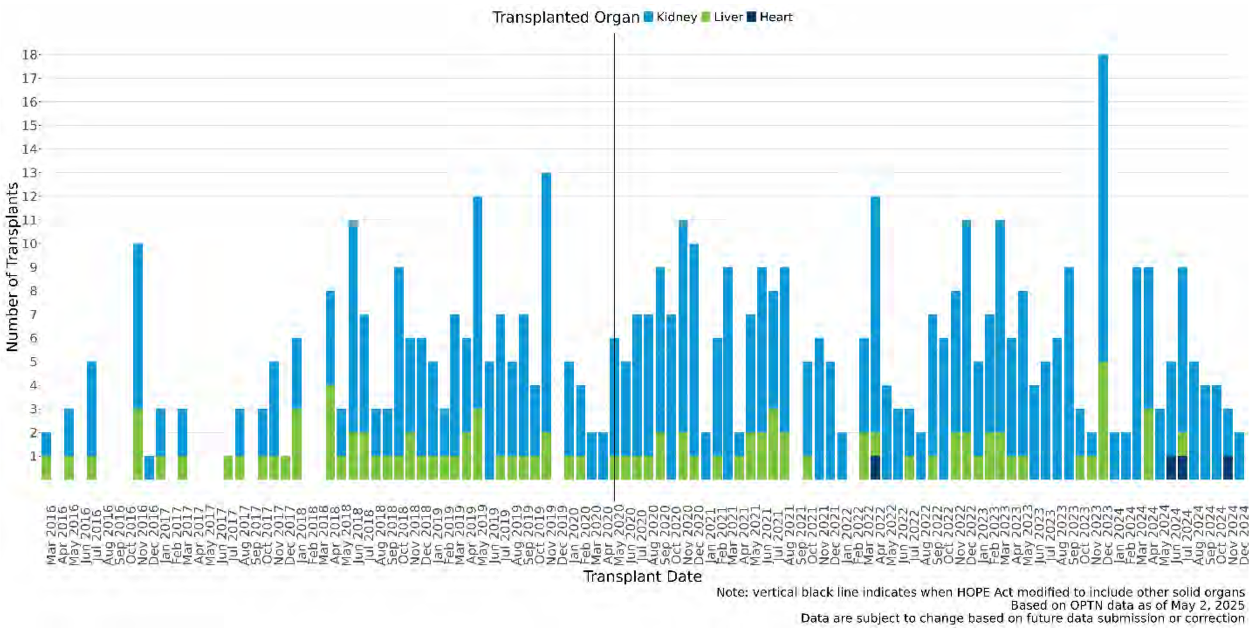
[37] Health and Human Services Department, "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act", 89 FR 93484 (11/27/2024).

[38] 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", 89 FR 106542

[39] OPTN Final Report. "HOPE Act Update: 2024Q4" Submitted to the Health Resources and Services Administration, January 21, 2025.

[40] Ibid.

Figure 1: OPTN HOPE Act Variance Transplants by Month and Organ Transplanted[41]



Additional Patient Safety Measures

While the HOPE Act has successfully allowed access to transplant for individuals living with HIV, this access has been restricted in a way that recent regulations have changed. Specifically, the amended Final Rule and revised NIH research criteria potentially expands access for two groups of individuals:

- Kidney, liver, and liver-kidney candidates living with HIV who are listed at transplant programs that are not currently participating in the OPTN HOPE Act Variance; and
- Non-kidney and non-liver candidates living with HIV who are at transplant programs that would not have been able to meet previous NIH research criteria requirements (for example, the requirement of five transplants of organs from donors who do not have HIV to candidates living with HIV over a four-year period).

The potential increase in access for these candidates is beneficial, but it does raise questions of patient safety: transplant programs that may have less experience with HOPE Act transplants now have the opportunity to perform these transplants. Liver and kidney transplant programs no longer have to meet the research criteria outlined by NIH in order to conduct HOPE Act transplants, so added safety measures address this potential risk as well. The DTAC considers issues related to the transmission of disease through organ transplantation, and thus seeks to ensure adequate patient safety measures are maintained as access to transplants for individuals with HIV expands. The DTAC considered the amended OPTN Final Rule, updated NIH research criteria, and HRSA directives when it voted to include the additional patient safety measures identified in this proposal for public comment.[42] Specifically, the DTAC voted to add the following measures in OPTN policy to support patient safety as new programs

[41] OPTN data as of May 2, 2025.
[42] Meeting Summary for January 14, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/ufbmtbk1/20250114_dtac_summary.pdf (Accessed May 7, 2025)

with potentially less experience have the opportunity to perform transplants of livers, kidneys, and liver-kidneys from donors with HIV to recipients living with HIV:

- Verification in the medical record by a transplant physician of candidate status and willingness to accept an organ from a donor with HIV (15.7.B and 15.7.C);
- That a transplant physician is the individual who verifies candidate HIV status and willingness to accept an organ from a donor with HIV after a test indicates the donor has HIV (15.3.B);
    - The process for verifying HIV status and willingness an organ after a test indicates the donor has HIV is not new; the fact that a transplant physician is the individual to verify candidate status and willingness to accept the organ is an addition to policy
- That a transplant surgeon and another licensed healthcare professional attest to the candidate HIV status and the candidate's willingness to accept an organ from a donor with HIV prior to transplantation (5.8.A and 5.8.B).

Patient safety is also supported by the post-public comment change to update informed consent requirements for living kidney and liver donors with HIV.

KPD Considerations

Kidney paired donation was not historically included in the HOPE Act, but it is not specifically excluded in the recent amended OPTN Final Rule. Also, the amended OPTN Final Rule no longer requires HOPE Act kidney transplants to be conducted as research, which effectively ended the variance and NIH research criteria requirements for living and kidney programs, a deliberate effort to broaden access. However, the nature of KPD programs are unique and require special consideration. Specifically, the DTAC reviewed several areas of KPD policy that would need additional consideration in consultation with subject matter experts from the OPTN Kidney Committee or OPTN KPD Workgroup to develop appropriate policy changes:

- What type of HIV testing should be required for KPD candidates
- When the HIV testing results would need to be available for matching purposes
- Whether HIV testing must be repeated a certain amount of time after the initial evaluation

To ensure patient safety is maintained while these questions are outstanding, DTAC decided not to propose changing OPTN KPD policy except to clarify that *Policy 15.7.B: Transplant Program Requirements for Transplantation of Organs from Donors with HIV* applies only to deceased donor match runs. DTAC noted the need for Kidney Committee consideration of possible options for addressing the above questions, and their overall thoughts on whether the KPD system is appropriate and safe for transplanting pairs of individuals with HIV.

Proposal for Board Consideration

In accordance with the amended OPTN Final Rule and NIH Final Notice, and consistent with HRSA's directive to the OPTN, modifications to OPTN policy for transplantation of organs from donors with HIV to recipients living with HIV include:

- Adjustments to reflect that kidney, liver, and liver-kidney transplants no longer need to meet research criteria or be conducted through an open variance for HIV transplantation;

- Ensuring patient safety is maintained by adding the following safeguards for liver, kidney, and liver-kidney candidates:
    - Documentation in the medical record by a transplant physician of candidate HIV status and candidate willingness to accept an organ from a donor with HIV; this must occur prior to the double verification process already in policy (15.7.B and 15.7.C),
    - That a transplant physician is the individual who verifies candidate HIV status and willingness to accept an organ from a donor with HIV after a test indicates the donor has HIV (15.3.B),
    - That a transplant surgeon and another licensed healthcare professional attest to the candidate HIV status and the candidate's willingness to accept an organ from a donor with HIV prior to or upon organ receipt for transplantation (5.8.A and 5.8.B);
- Ensuring patient safety is maintained by adding new informed consent requirements for living kidney and liver donors with HIV;
- Modifying language to be respectful of individuals living with HIV and consistent with the use of "living with HIV" terminology in the amended OPTN Final Rule;
    - Note – this modification of language does not change to whom the individuals refer: these are still individuals that have had at least one test that is positive for HIV
- Cross-references are included for clarity and to avoid confusion;
- *Policy 2.7.A: Exceptions to HIV screening requirement* is eliminated from policy as it is inconsistent with patient safety goals, and technological advances in HIV testing and organ preservation indicate such an exception is no longer necessary;[43,44] and
- Reporting of data safety monitoring reports by transplant programs participating in the HOPE Act variance is clarified to be upon request by the OPTN (15.7.D).

Overall Sentiment from Public Comment

The OPTN public comment period provides the opportunity for OPTN members to submit a substantive written comment about the proposal overall, or specific components. The proposal was available for public comment from March 21 through April 22, 2025. As part of the public comment proposal, the Committee requested community feedback about the following[45]:

- Whether the community considers that the additional safety requirements being proposed are
    - o Adequate and appropriate, or
    - o Insufficient - additional patient safety measures should be considered (if so, please specify what additional patient safety measures should be added), or

[43] OPTN Organ Procurement Organization Committee Leadership Call, January 2025.
[44] OPTN Ad Hoc Disease Transmission Advisory Committee Leadership Call, January 2025.
[45] *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates*, OPTN Ad Hoc Disease Transmission Advisory Committee, March 2025, https://optn.transplant.hrsa.gov/media/a5kc04xq/hope_proposal_mar25_pc_.pdf (Accessed May 2, 2025).

    - Unnecessary and resource-intensive (if so, please explain any concerns about burden, which specific patient safety measures are unneeded, and why they are unneeded / how patient safety is already adequate)
- If there are any questions about implementation, logistics, or training that can be addressed prior to implementation.

Feedback about the proposal was collected through the OPTN website and by email. Sentiment was measured on a 5-point Likert scale from strongly oppose to strongly support (1-5). Figure 2 shows overall sentiment, with no opposition or neutral responses from those who provided their response. The overall total sentiment score of 4.7 indicates that public comment sentiment has been supportive of the changes described in this proposal.

Figure 2: Overall Sentiment

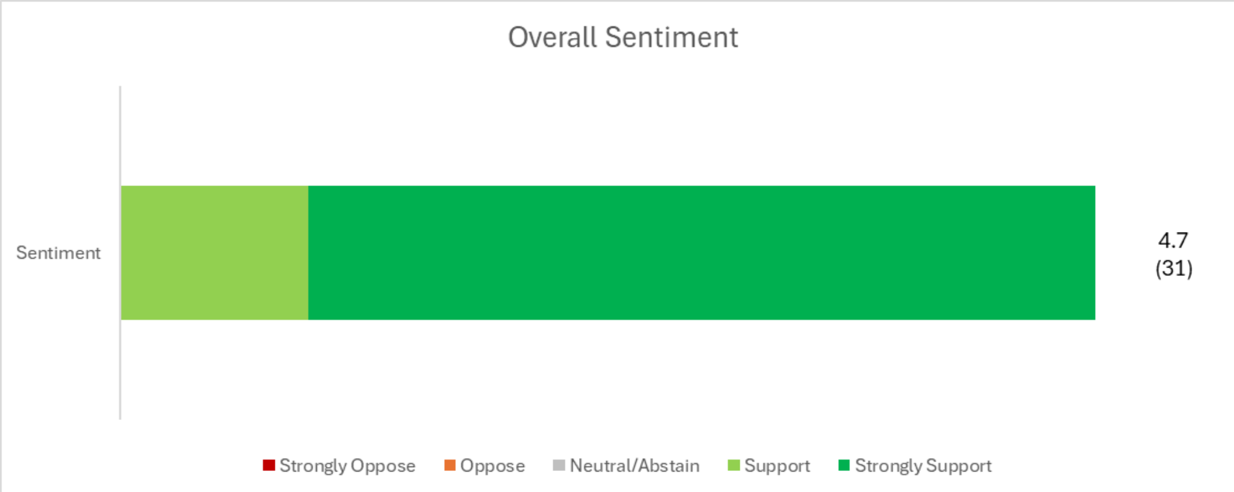
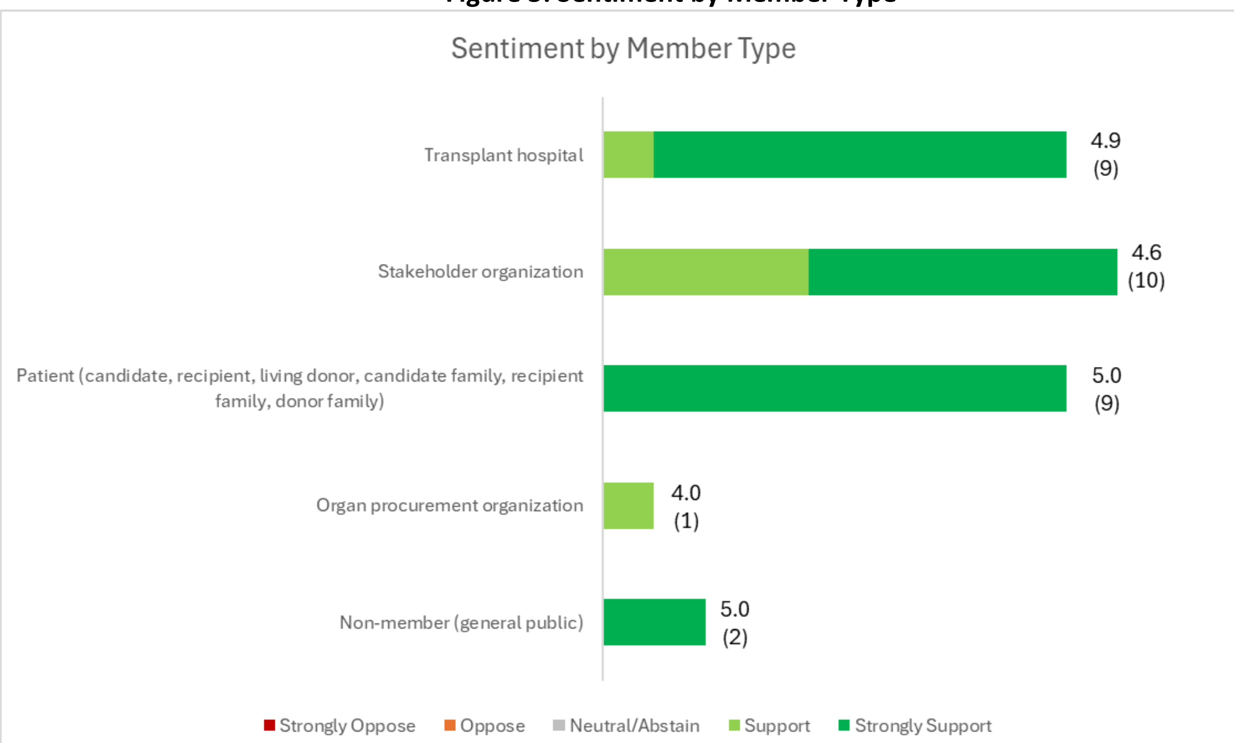


Figure 3 shows sentiment by member type. Most sentiment received was from patients, transplant hospitals, and stakeholders, all of whom supported the proposal.

Figure 3: Sentiment by Member Type



One stakeholder weighed in after public comment and that feedback is described in the section below, “Living Donors with HIV.”

Themes in Public Comment

Support for Aligning OPTN Policy with Federal Changes and Including Additional Patient Safety Measures

There was significant support for aligning OPTN policy with federal regulations and enhancing patient safety measures. The proposal received support from the OPTN Patient Affairs, Kidney, and Liver Committees, three patients, 11 other individuals, an OPO, and four transplant hospitals. **Table 2** illustrates the stakeholder organizations that endorsed the proposal in both its alignment with federal changes and inclusion of additional patient safety measures. Public comments indicated strong approval for removing the NIH research criteria requirements for kidney and liver transplants, as this change would increase access to organ transplantation. Additionally, there was widespread support for the proposed patient safety measures.

Table 2: Stakeholder Organizations in Support of Aligning OPTN Policy with Federal Changes and Including Additional Patient Safety Measures

Stakeholder Organizations
American Society of Transplant Surgeons (ASTS)
American Society of Nephrology (ASN)
North American Transplant Coordinators Organization (NATCO)
The Association for Multicultural Affairs in Transplantation (AMAT)
National Kidney Foundation (NKF)
American Society for Histocompatibility and Immunogenetics (ASHI)
Association of Organ Procurement Organizations (AOPO)

Feedback included in these comments noted the importance of "combat[ing] stigma around HIV," "ensuring consistency and protection" for transplant candidates, and removing barriers for "historically marginalized communities."[46] Commenters also noted the benefit of "increasing the pool of transplantable organs, a win for all."[47] DTAC considered this feedback and support for the intended changes in their decision to minimize changes to policy language post-public comment.

Potential Burden of Patient Safety Measures

A few comments raised concerns about the potential burden associated with the proposed patient safety measures. ISHLT supported aligning OPTN policy with the amended OPTN Final Rule and revised NIH research criteria, but was concerned about the level of verification for candidates introduced by the proposal, and cautioned against implementing similarly stringent measures for heart and lung programs in the future to avoid deterring center participation without demonstrable improvements in patient safety. A patient also indicated concern about the level of burden being a barrier to patient access to transplant. These comments were in the minority but indicate that the support for patient safety

[46] Public Comments on *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates*. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/revisions-to-human-immunodeficiency-virus-hiv-policies-to-align-with-federal-regulatory-updates/ (Accessed May 2, 2025).
[47] Ibid.

measures was not unanimous, like the support for aligning with amended OPTN Final Rule and NIH Final Notice was.

DTAC considered these comments but ultimately affirmed their support for including additional patient safety measures. To maintain the patient safety record maintained by HOPE Act transplants to date, DTAC considered that these measures ensure access expands only in conjunction with clinical affirmation of candidate status and willingness to receive an organ from a donor with HIV at multiple, distinct points prior to transplant.

Living Donors with HIV

Feedback from the American Society of Transplantation (AST) indicated this stakeholder generally supported the proposal but had specific concerns about removing the clinical research criteria and HOPE Act variance participation requirements for living kidney and liver transplants when both donor and candidate have HIV. AST cited the lack of significant data on living donors with HIV, and the need for more data on long-term outcomes for this population. The Living Donor Committee expressed similar concern when they reviewed the proposal, suggesting in a memo to the DTAC that informed consent for living donors with HIV include disclosure of this lack of data (to date, there have been three living donor HOPE Act transplants).[48,49] The Living Donor Committee also recommended collaborating with the Scientific Registry of Transplant Recipients (SRTR) to monitor and collect data for living donors with HIV, suggesting that these longer-term outcomes are tracked and analyzed to provide valuable insight into the safety and efficacy of the policy.

The DTAC appreciated the feedback from AST and the Living Donor Committee, agreeing that living kidney and liver donors with HIV should be fully aware of the available data and the fact that long term outcomes related to donating while living with HIV are unknown. As NIH research criteria and OPTN HOPE Act variance requirements are removed for kidney and liver transplants from living donors with HIV to recipients living with HIV, updating informed consent requirements in OPTN policy promotes living donor safety. The DTAC modified the proposal post-public comment to add an element specific to informed consent for living kidney and liver donors with HIV to policy. DTAC agreed that outcomes for living donors with HIV should be followed long-term, which aligns with the Living Donor Committee's effort to improve data collection on all living donors and their collaboration with the SRTR on long-term data collection for living donors.

Compliance Analysis

NOTA and OPTN Final Rule

This proposal is submitted under the authority of NOTA, which requires that the OPTN adopt and use standards with respect to organs from donors with HIV, "provided that any such standards ensure that organs … with HIV may be transplanted only [pursuant to this section],"[50] and the OPTN Final Rule, which similarly requires that "the OPTN shall adopt and use standards of quality with respect to organs

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[48] OPTN Living Donor Committee Memo: *Comments concerning the Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates proposal*. April 24, 2025. The Living Donor Committee met the day after public comment had already ended, so submitted their feedback in a memo to the DTAC.
[49] OPTN Final Report. "HOPE Act Update: 2024Q4" Submitted to the Health Resources and Services Administration, January 21, 2025.
[50] 42 USC §274(b)(3).

from individuals … with HIV to the extent the Secretary determines necessary…"[51] and that "[i]f the Secretary has determined …that participation in clinical research is no longer warranted as a requirement for transplantation of organs from donors with HIV, the OPTN shall adopt and use standards of quality with respect to organs from donors with HIV as directed by the Secretary, consistent with 42 U.S.C. 274, and in a way that ensures the changes will not reduce the safety of organ transplantation."[52]

Further, the preamble to the amended OPTN Final Rule "directs the OPTN to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that, from the OPTN's expertise, will not reduce the safety of HOPE Act kidney and liver transplants, provide appropriate oversight for these transplants, and require sufficient data collection and outcomes monitoring."[53] This proposal extends existing safety measures for HOPE Act kidney and liver transplants by adding pre-transplant verification of recipient HIV status, requiring specific personnel for verification of recipient HIV status, and informed consent documentation. It identifies an outcomes monitoring plan described in the section below, Post-Implementation Monitoring.

The OPTN Final Rule specifies that "the OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans."[54] As detailed in the Policy Monitoring section below, the OPTN will continue to include quarterly data reports to HRSA detailing all candidates listed, donors recovered, and transplants performed as part of the HOPE Act variance (all variances are by definition experimental and not generalized policy). The OPTN may request data safety monitoring reports from transplant programs participating in the variance to supplement OPTN data in assessing the impact of non-kidney and non-liver transplants from donors with HIV to recipients living with HIV. The Secretary will continue to annually "review the results of scientific research with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV…" for non-kidney and non-liver organs.[55]

OPTN Strategic Plan

This project aligns with the OPTN Strategic Plan goal of increasing opportunities for transplants. It would expand access for individuals living with HIV by allowing transplants of livers, kidneys, and liver-kidneys from donors with HIV to candidates living with HIV without requiring compliance with the NIH research criteria or participation in the OPTN HOPE Act variance. Since 2013, the HOPE Act has resulted in over 500 transplants that may not have otherwise occurred. These policy changes may expand access for any individuals living with HIV that are listed for transplant at one of the 207 kidney and 125 liver programs

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[51] 42 CFR § 121.6(b)(2)
[52] 42 CFR § 121.6(b)(3)
[53] 42 FR 93484
[54] 42 CFR § 121.8 (g)
[55] 42 USC §274f-5(c)(1)

that have not participated in the HOPE Act variance to date.[56] These changes are in alignment with federal law and support increased access for individuals with HIV while maintaining patient safety.

[56] Because programs would only be participating if they had individuals living with HIV at their transplant program who were willing to accept a liver or kidney from a donor with HIV, the number of additional programs that participate in transplants of organs with HIV will likely be much smaller than the total number of programs that could, in theory, participate.

Implementation Considerations

Transplant programs and the OPTN would need to take action to implement this proposal. This proposal is anticipated to have limited impact on organ procurement organizations and is not anticipated to affect the operations of histocompatibility laboratories.

Transplant Programs

Operational Considerations for all Organs

Current Policy 15.7.C (15.7.B in the proposed changes) already requires double verification for all organs to certify that the candidate is living with HIV and willing to accept an organ from a donor with HIV; this requirement will be maintained.

The OPTN Waiting List label for candidates living with HIV and willing to accept an organ from a donor with HIV will be changed from "HOPE Act IRB Research" to "Human Immunodeficiency Virus (HIV)," since this question will apply to all organs, including kidneys and livers that no longer require IRB research participation. In accordance with using respectful and non-stigmatizing language referencing individuals with HIV, the question posed underneath the label will be updated to ask whether the candidate is living with HIV and willing to accept an organ from a donor with a positive HIV test.

The OPTN computer system will continue to default the response to 'No' for willingness to accept HIV positive organ offers for new and currently listed patients.

The current OPTN policy applicable to HOPE Act transplants will continue to apply to transplant programs wishing to transplant kidneys and livers from donors with HIV to candidates living with HIV until implementation of these changes, which is planned for June 26th, 2025. The OPTN provided a communications notice about these provisions, which will continue to apply for non-kidney and non-liver organs, and noted that:[57]

- These requirements apply even if the transplant program has a single transplant candidate, or a small group of candidates, who may qualify for transplantation under the HOPE Act.
- If the program intends to list and treat only a single candidate, the OPTN will accept an institutional review board (IRB)-approved research protocol for a single candidate, as long as all other standards are met.
- There is no specific restriction on pediatric candidates, so an IRB-approved research protocol that includes provisions for pediatric candidates is acceptable as long as all other standards are met.

Operational Considerations for Kidney and Liver Transplant Programs

Implementation changes for kidney and liver transplant programs include:

[57] OPTN Communications, *Clarification – HOPE Act IRB protocols and individual IRB candidate applicability*. May 14, 2025. https://optn.transplant.hrsa.gov/news/clarification-hope-act-irb-protocols-and-individual-irb-candidate-applicability/

- All living and deceased kidney and liver transplant programs will be updated in the OPTN Membership System to be marked as “approved” for performing transplants for candidates living with HIV if the donor also has HIV.
    - Once these programs are approved, transplant program security administrators will be able to grant permission to users at their centers to verify that a candidate is living with HIV and willing to accept an HIV organ in the OPTN Waiting List.
        - A new requirement for kidney, liver, and liver-kidney candidates will be for a transplant physician to verify and document in the medical record that the candidate is living with HIV and willing to accept an organ from a donor with HIV. This must occur prior to the two-person reporting and verification process in the OPTN Waiting List (15.7.B and 15.7.C).
    - Once the candidate verification process is completed, the candidate will be eligible to appear on the match run for HIV donors.
- For kidney, liver, and liver-kidney candidates, if a transplant program has previously indicated in the OPTN Waiting List that a candidate is living with HIV and willing to accept an organ from a donor with HIV, then upon implementation the transplant physician must re-verify in the candidate’s medical record that the candidate has HIV and is willing to accept an organ from a donor with HIV. Confirmation that this re-verification of candidate status and willingness to accept an organ from a donor with HIV is documented in the candidate’s medical record will occur through routine site survey. If the program identifies a change in candidate status or willingness to accept an organ from a donor with HIV, the program must update the OPTN Waiting List so that the candidate no longer shows as eligible for offers of organs from donors with HIV. Put another way, no modification is needed in the OPTN Waiting List unless candidate status or willingness to accept an organ from a donor with HIV has changed.

- A small number of liver and kidney candidates verified as living with HIV and willing to accept an HIV positive organ are listed at programs with a previous (but not current) IRB approved research protocol. Prior to implementation, these candidates will not be receiving organ offers from donors with an HIV positive test because the program does not have a current IRB approved research protocol in place. DTAC leadership confirmed that for this subset of candidates it is appropriate for patient safety reasons to reset each of these liver and kidney candidates to require another verification of their willingness to accept an organ from a donor with an HIV positive organ. Requiring a verification in the system will ensure that those candidates do not suddenly begin receiving organ offers from donors with an HIV positive test result when the removal of the requirement for an IRB approved research protocol is implemented before the program can ensure the candidates willingness to accept an organ from a donor with an HIV positive test. The candidates will remain active on the list while awaiting verification and will be eligible to receive organ offers from donors without an HIV positive result. Waiting time is not dependent on the reverification, and once reverified, these patients will receive organ offers without impact to waiting time or their position on the match. Outreach by the OPTN Contractor will ensure the transplant programs and their candidates are aware of the verification requirement ahead of implementation.
- When a candidate receives an organ offer from a donor with a positive HIV test, a transplant physician must be the individual who confirms candidate HIV status and obtains informed consent (15.3.B)

  - The informed consent process is already in policy, but the fact that a transplant physician must obtain the informed consent is new.

- Prior to transplantation, a transplant surgeon and a licensed healthcare professional must attest to HIV status of donor and candidate, and that the candidate is willing to accept an organ from a donor with HIV (5.8.A and 5.8.B)
  - This is a new requirement and would be documented in the medical record.
- Living kidney or liver programs must consent their living donors with HIV about the lack of data around long-term outcomes for individuals living with HIV and donating an organ (14.3)

Fiscal Impact

This proposal is expected to have a low fiscal impact on transplant hospitals, as additional education will be needed to notify staff of policy changes, but overall would not require new staffing. New protocols will need to be documented by staff but will have low impact due to very low volume nationally. The addition of the physician attestation will be low impact for the volume affected.

Organ Procurement Organizations (OPOs)

Operational Requirements

Requirements for OPOs allocating organs from deceased donors with HIV (Policy 15.7.A) have been modified to reflect that only non-liver and non-kidney organs require participation in an IRB-approved research protocol that meets the requirements in the NIH research criteria. It is important to note for OPOs that OPTN *Policy 2.7.A: Exceptions to HIV Screening Requirement* is being eliminated from policy to ensure patient safety protocols are maintained. Feedback from the OPTN DTAC and OPO Committee leadership teams indicated the policy was of historical use but that it was no longer relevant due to pulsatile preservation availability for organs and rapid donor testing.[58]

Fiscal Impact

This proposal is expected to have no fiscal impact on OPOs and a low impact on staff, ensuring practices and documentation are in place.

OPTN

Operational Requirements

Upon implementation, all living and deceased kidney and liver transplant programs will be marked as "approved" for performing transplants from donors with HIV to candidates living with HIV in the OPTN membership system. To ensure continued compliance with recent updates, an ongoing effort to maintain system alignment with the latest policy language will require additional modifications to the OPTN computer system. Help documentation will be updated upon implementation as well.

The OPTN will also share updated FAQs, produce an educational webinar and provide other resources such as training modules to ensure community awareness and adequate preparation for these changes. The OPTN will focus communications and training for both living and deceased donor liver and kidney

[58] 1.10.25 OPTN OPO leadership call; 1.10.25 OPTN DTAC leadership call.

programs. It will consider how best to communicate the changes to patients, in accordance with Patient Affairs Committee feedback.

Resource Estimates

It is estimated that $125,788 would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the updated policy requirements and associated system tools. In addition, implementation would include building communications and education materials, updating process documents, and community outreach. It is estimated that $37,906 would be needed for ongoing support. Ongoing support includes member support and education, compliance monitoring, system maintenance, and answering member questions as necessary. In addition, ongoing support will include a monitoring report at the 6-month, 1-year, and 2-year timeframes. The total for implementation and ongoing support is estimated to be $163,694. [59]

Post-implementation Monitoring

Member Compliance

An OPTN Contractor will continue to review and assess all instances of organ transplants from donors with HIV to ensure compliance with all policy requirements. For example, this would include instances where a candidate is registered for multiple organs and has discrepant responses between the organ registrations on willingness to receive an organ from a donor with HIV. During site surveys of transplant hospitals, an OPTN Contractor will review a sample of medical records, and any material incorporated into the medical record by reference, to verify compliance with the following for all kidney, liver, and liver-kidney candidates and transplants:

- Verification of HIV status of the donor and candidate prior to organ receipt (Policy 5.8.A) and upon organ receipt (Policy 5.8.B) by a transplant surgeon and a licensed healthcare professional;
- Confirmation from a transplant physician the candidate is living with HIV and obtained informed consent, in cases where the donor tests positive for HIV according to table 15-1 in Policy 15.3.B; and
- Verification by a transplant physician that the candidate is living with HIV and willing to accept an organ from a donor with HIV prior to the two-person reporting process in policies 15.7.B and 15.7.C.
- For living donors with HIV, that the program disclosed to the living kidney or liver donor with HIV that long-term outcomes for individuals living with HIV and donating an organ are unknown.

This proposal will not change the current routine monitoring of OPTN members for all non-kidney and non-liver candidates and transplants that would meet the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV.*

[59] Resource estimates are calculated by the current contractor for that contractor to perform the work. estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

Policy Evaluation

<u>Kidneys, Livers, and Kidney-Livers</u>

The DTAC will receive monitoring reports at six months, one year and two years following the policy change.

Metrics to be evaluated include:

- Waiting List
  - The number of waiting list registrations indicated as willing to accept a kidney, liver, or liver-kidney from a donor with HIV, post-policy by the following stratifications as sample size allows:
    - Organ type
    - Demographics (age, birth sex, race/ethnicity)
    - OPTN region
    - Transplant program
  - Waiting list removals for registrations ever indicated as willing to accept a kidney, liver, or liver-kidney from a donor with HIV, post-policy by the following stratifications as sample size allows:
    - Organ type
    - Reason for removal
    - Demographics (age, birth sex, race/ethnicity)
    - OPTN region
    - Transplant program
- Transplants
  - Number of transplants to recipients living with HIV from donors with HIV, post-policy, by the following stratifications as sample size allows:
    - Organ type
    - Donor type (living or deceased)
    - Demographics (age, birth sex, race/ethnicity)
    - OPTN region
    - Transplant program
- Post-transplant graft survival for transplants for recipients living with HIV from donors with HIV compared to transplants for recipients without HIV from donors without HIV, as sample size allows
- Post-transplant patient survival for transplants for recipients living with HIV from donors with HIV compared to transplants for recipients without HIV from donors without HIV, as sample size allows
- Volume of recipient cases with proven/probable potential donor derived disease transmission events (PDDTE) involving donors with HIV submitted through the OPTN Computer System Improving Patient Safety Portal and reviewed by the DTAC
- Donors
  - Kidney, liver and liver-kidney donors recovered with a positive HIV test, post-policy, by the following stratifications as sample size allows:
    - Donor type
    - Demographics (age, birth sex, race/ethnicity)
    - OPTN region

        - Recovering OPO
        - KDPI
    - Kidney, liver and liver-kidney deceased donor non-use rate for donors recovered with a positive HIV test compared to donors recovered with no positive HIV test, post-policy
    - Kidney, liver and liver-kidney deceased donor utilization rate for donors recovered with a positive HIV test compared to donors recovered with no positive HIV test, post-policy
- Other metrics as requested by the DTAC

Non-Kidney and Non-Liver Organs

Monitoring for the open variance for the recovery and transplantation of non-kidney and non-liver organs from donors with HIV will not change with this implementation. The OPTN will continue to provide quarterly reports to HRSA. Kidney, liver, and liver-kidney candidates, donors, and transplants for programs participating in the HOPE Act open variance prior to implementation will continue to be included in monitoring reports for the variance. These reports include all candidates listed, donors recovered, and transplants performed as part of the HOPE Act open variance since its implementation into OPTN Policy. Following implementation, only non-liver and non-kidney metrics will be included in the variance monitoring reports (excepting the historical data described above). The OPTN may request data safety monitoring reports from transplant programs participating in the variance to supplement OPTN data in assessing the impact of non-kidney and non-liver transplants from donors with HIV to recipients living with HIV.

Conclusion

Since the inception of the HOPE Act, there have been over 500 transplants of organs from donors with HIV to recipients living with HIV and zero patient safety events.[60] The policy and system changes described in this proposal reflect updates to continue to maintain patient safety as HOPE Act kidney, liver, and liver-kidney transplants no longer require adherence to the NIH research criteria, to reflect other changes outlined in the amended OPTN Final Rule and the revised NIH research criteria, and to reflect both the support received during public comment and identified changes for living liver and kidney donor informed consent.

[60] OPTN data as of January 10, 2025.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1.2 Definitions

Eligible Death

Eligible death

For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets *all* the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m^2 or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
    - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Greater than 70 years old
        - Age 50-69 years with history of type 1 diabetes for more than 20 years
        - Polycystic kidney disease
        - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
        - Terminal serum creatinine greater than 4.0 mg/dL
        - Chronic renal failure
        - No urine output for 24 hours or longer
    - The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Cirrhosis
        - Terminal total bilirubin greater than or equal to 4 mg/dL
        - Portal hypertension
        - Macrosteatosis greater than or equal to 50% or fibrosis greater than or equal to stage II
        - Fulminant hepatic failure
        - Terminal AST/ALT greater than 700 U/L
    - The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Greater than 60 years old
        - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
        - History of coronary artery bypass graft (CABG)
        - History of coronary stent/intervention
        - Current or past medical history of myocardial infarction (MI)
        - Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease)

        - Acute myocarditis or endocarditis, or both
        - Heart failure due to cardiomyopathy
        - Internal defibrillator or pacemaker
        - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
        - Serial echo results showing severe global hypokinesis
        - Myxoma
        - Congenital defects (surgically corrected or not)
    - The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Greater than 65 years old
        - Diagnosed with COPD
        - Terminal PaO_2/FiO_2 less than 250 mmHg
        - Asthma (with daily prescription)
        - Asthma is the cause of death
        - Pulmonary fibrosis
        - Previous lobectomy
        - Multiple blebs documented on computed axial tomography (CAT) scan
        - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
        - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an eligible death unless the donor meets *any* of the following criteria:

- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits *any* of the following active infections (with a specific diagnosis):
    - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
    - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute Epstein Barr virus (mononucleosis), West Nile virus infection, or SARS. However, an ~~HIV positive~~ organ procured from a donor with HIV for transplantation into a~~n~~ ~~HIV positive~~ recipient living with HIV at a transplant hospital that meets the requirements in *Policy 15.7: ~~Open Variance for the~~ Recovery and Transplantation of Organs from ~~HIV Positive~~ Donors with HIV* would still meet the requirements of an eligible death~~, according to the OPTN Final Rule~~.
    - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
    - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp.*)
    - Prion: Creutzfeldt-Jacob disease

2.7 HIV Screening of Potential Deceased Donors

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV according to *Policy 2.9: Required Deceased Donor Infectious Disease Testing*.

The host OPO must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs. Allocation of organs from deceased donors with HIV must follow the requirements in *Policy 5.5.C: OPO Requirements for Positive HIV Test Results* and *Policy 15.7.A: Requirements for Allocating Organs from Deceased Donors with HIV*.

~~2.7.A Exceptions to HIV Screening Requirement~~

~~Exceptions to the HIV screening requirement may be made for organs *other than* kidneys, when, in the medical judgment of the host OPO and recipient transplant hospital or OPO, an extreme medical emergency warrants the transplantation of an organ that has not been tested for HIV.~~

~~In this case the host OPO must do *both* of the following:~~

1. ~~Provide all available deceased donor medical and social history to the transplant program.~~
2. ~~Treat the deceased donor as having any risk criteria for acute HIV, HBV or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*.~~

~~In this case the receiving transplant hospital must:~~

- ~~Inform the potential transplant recipient or the recipient's authorized agent before transplantation according to *Policy 15.3.B: Donors with Risk Identified Pre-Transplant*~~
- ~~Obtain HIV screening test results prior to storing, sharing, or using the extra vessels in another recipient, according to *Policy 16.6: Extra Vessels Transplant and Storage*~~

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Human Immunodeficiency Virus (HIV); Organs from ~~HIV-positive~~ donors with HIV may only be recovered and transplanted according to the requirements in *Policy 15.7: Recovery and Transplantation of Organs from Donors with HIV* ~~the requirements in the Final Rule~~	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA

5.3.D Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

i. The maximum number of mismatched antigens it will accept for any of its liver candidates
ii. Minimal acceptance criteria for livers
iii. Acceptance criteria for expedited offers as outlined in *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria*
iv. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non-A_1
v. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
vi. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
vii. If a candidate will accept a liver for other methods of hepatic support
viii. If a candidate is willing to accept a segmental graft

ix. If a candidate living with HIV is willing to accept a~~n~~ liver from a donor with HIV ~~positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule~~

5.3.H Kidney Offer Filters

The OPTN generates model-identified offer filters for all kidney transplant programs based off of a program's transplantation behavior within the most recently available 365 days of data. New model-identified filters will be generated and enabled for each transplant program every six months. A model-identified offer filter is generated for a program if all of the following criteria are met:

• The program declined all kidney offers on at least 20 donors that met the filter criteria,
• The program transplanted 0 donors that met the filter criteria, and
• The kidneys that meet the filter criteria were transplanted elsewhere

All model-identified offer filters will automatically not apply to candidates with any of the following criteria at the time of the match run:

• Greater than 90% CPRA,
• 0-ABDR mismatch,
• in medically urgent status, or
• less than 18 years old

Model-identified offer filters will be applied to all adult kidney transplant programs. Pediatric alone programs may manually apply model-identified filters.

All programs may remove their model-identified filters or modify automatic candidate exclusion criteria of their model-identified filters. Any program may create their own program-identified filters.

Model-identified and program-identified offer filters will not be applied to kidney match runs from a~~n HIV positive~~ donor with HIV.

5.4.E Allocation to Candidates Not on the Match Run

When a candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant hospital must document the reason the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations or to prevent organ waste.

In such an event, the transplant hospital must document all of the following:

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. Prior to transplant, the transplant hospital must verify the medical suitability between the

deceased donor organ and recipient in at least, but not limited to, all the following areas according to organ type:

- Blood type
- Blood subtype, when used for allocation
- Donor HLA and candidate's unacceptable antigens
- Donor height
- Donor weight
- Infectious disease test results
- For ~~HIV positive~~ deceased donors with HIV, the OPO and transplant ~~hospital~~ program must also do both of the following:
    - ~~a)~~ Verify that the potential recipient is ~~registered as a HIV positive candidate~~ living with HIV and willing to accept an organ from a donor with HIV ~~at a transplant hospital that meets the requirements in OPTN Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs~~
    - *b)* Meet the requirements in OPTN *Policy 15.7: ~~Open Variance for the~~ Recovery and Transplantation of Organs from ~~HIV Positive~~ Donors with HIV*

The transplant hospital must maintain all related documentation.

5.5.C OPO Requirements for Positive HIV Test Results

If a donor is found to ~~be~~ have a positive test result for HIV after any match run has been executed, the host OPO must report the updated information on the donor with HIV to the OPTN and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute match runs in order to include *only* ~~HIV-positive~~
    - ~~i.~~ Kidney, liver, or liver-kidney candidates living with HIV who are willing to accept organs from donors with HIV, and
    - ~~ii.~~ Non-kidney or non-liver candidates living with HIV who are participating in an institutional review board (IRB) approved research protocol that meets the requirements in the National Institutes of Health (NIH) Final Notice ~~Rule~~ regarding the recovery and transplantation of organs from donors ~~individuals known to be infected~~ with HIV and the requirements outlined in ~~according to~~ *Policy 15.7.D~~A~~: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver ~~Requirements for Allocating HIV-positive Deceased Donor~~ Organs from Donors with HIV.*
3. Withdraw any pending offers to candidates who are not ~~HIV positive~~ living with HIV.
4. Withdraw any pending offers to non-kidney and non-liver candidates who are not also participating in an ~~institutional review board~~ IRB-approved research protocol that meets the requirements in the ~~OPTN~~ NIH Final Notice ~~Rule~~ and the requirements outlined in ~~according to~~ *Policy 15.7.~~C~~D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver ~~Transplant Hospital Requirements for Transplantation of HIV Positive~~ Organs from Donors with HIV*
5. Continue allocating organs using the re-executed match run. Only recover and send extra vessels from this donor with an organ allocated from this donor.

5.8 Pre-Transplant Verification

Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.

5.8.A Pre-Transplant Verification Prior to Organ Receipt

If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

1. The intended recipient must be present in the operating room
2. The verification must occur *either*:
    a. Prior to induction of general anesthesia
    b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information according to *Table 5-2* below. Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

Table 5-2: Pre-Transplant Verification Prior to Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least one of the following:	By *both* of the following individuals:
Expected donor ID	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected organ (and lung laterality if applicable)	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents • OPTN computer system	Two licensed health care professionals
Recipient unique identifier	• Recipient identification band	Two licensed health care professionals
Recipient blood type	• OPTN computer system • Recipient blood type and subtype source documents • Recipient medical record	Two licensed health care professionals
Expected donor and recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following	Two licensed health care professionals

	verification of donor and recipient blood types	
For kidneys and livers from donors with HIV, that the recipient is living with HIV and willing to accept an organ from a donor with HIV	• OPTN computer system • Recipient medical record • Attestation following verification of HIV status of donor and candidate	1. Transplant surgeon 2. Licensed health care professional

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

5.8.B Pre-Transplant Verification Upon Organ Receipt

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with *all* the following requirements:

1. The intended recipient must be present in the operating room
2. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information according to *Table 5-3* below. Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

Table 5-3: Pre-Transplant Verification Upon Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• External and internal organ package labels • Documentation with organ	1. Transplant surgeon 2. Licensed health care professional
Organ (and laterality if applicable)	• Organ received	1. Transplant surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for allocation)	1. Donor blood type and subtype source documents	1. Transplant surgeon 2. Licensed health care professional
Recipient unique identifier	• Recipient identification band	1. Transplant surgeon 2. Licensed health care professional

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Recipient blood type	• Recipient blood type source documents • Recipient medical record	1. Transplant surgeon 2. Licensed health care professional
Donor and recipient are blood type compatible (or intended incompatible)	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Transplant surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct recipient	• Recipient medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Transplant surgeon 2. Licensed health care professional
For kidneys and livers from donors with HIV, that the recipient is living with HIV and willing to accept an organ from a donor with HIV	• OPTN computer system • Recipient medical record • Attestation following verification of HIV status of donor and candidate	1. Transplant surgeon 2. Licensed health care professional

The transplant hospital must document that the pre-transplant verification upon organ receipt was completed according to the hospital's protocol and the above requirements.

14.3 Informed Consent Requirements

The living donor recovery hospital is responsible for obtaining and documenting informed consent prior to organ recovery. Informed consent requirements must include *all* of the components in *Tables 14-1* through *14-5*. Documentation of informed consent must be maintained in the living donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent:
Obtain from living donors	The living donor's signature on a document that confirms that the donor: 1. Is willing to donate 2. Is free from inducement and coercion 3. Has been informed that he or she may decline to donate at any time

The recovery hospital must:	**These elements of informed consent:**
Provide to living donors	1. An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential. 2. The ILDA must be available to assist the living donor during the consent process, according to *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* 3. Instruction about all phases of the living donation process, which includes: • Consent • Medical and psychosocial evaluations • Pre- and post-operative care • Required post-operative follow-up according to *Policy 18.4: Living Donor Data Submission Requirements.* Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital's staff.
Disclose to living donors	1. It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations. 2. The recovery hospital must provide an ILDA. 3. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation. 4. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs. 5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment. 6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient. 7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: • Exceed local or national averages • Do not necessarily prohibit transplantation • Are not disclosed to the living donor 8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: • The reasons for a transplant candidate's increased likelihood of adverse outcomes

The recovery hospital must:	These elements of informed consent:
	• Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law 9. Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. 10. The recovery hospital is required to: a. Report living donor follow-up information, at the time intervals specified in *Policy 18.5: Living Donor Data Submission Requirements* b. Have the donor commit to post donation follow-up testing coordinated by the recovery hospital. c. Obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease. 11. Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care: a. May need to be reported to local, state or federal public health authorities b. Will be disclosed to their recipient's transplant hospital c. Will be reported through the OPTN Improving Patient Safety Portal 12. A living donor must undergo a medical evaluation according to Policy 14.4: Medical Evaluation Requirements for Living Donors and a psychosocial evaluation as required by *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. 13. The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria 14. The following are inherent risks associated with evaluation for living donation: a. Allergic reactions to contrast b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the living donor e. Discovery of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team 15. There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or

The recovery hospital must:	These elements of informed consent:
	permanent and include, but are not limited to, *all* of the following: a. Potential medical or surgical risks: i. Death ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the living donor's lifestyle from donation c. Potential financial impacts: i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs ii. Need for life-long follow up at the living donor's expense iii. Loss of employment or income iv. Negative impact on the ability to obtain future employment v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

Table 14-2: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include: a. On average, living donors will have a 25-35% permanent loss of kidney function after donation. b. Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors. c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD. d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney. e. Dialysis is required if the living donor develops ESRD. f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.3: Kidney Allocation Points*.
Disclose to all living kidney donors	Surgical risks may be transient or permanent and include but are not limited to: • Decreased kidney function • Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
Disclose to all female living kidney donors	Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation
Disclose to all living kidney donors with HIV	The potential impact on their health and the long-term outcomes associated with donating an organ while living with HIV is unknown

Table 14-3: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery hospital must:	**These additional elements as components of informed consent for living liver donors:**
Disclose to all living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. • Biliary complications, including leak or stricture that may require additional intervention. • Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.
Disclose to all living liver donors with HIV	The potential impact on their health and the long-term outcomes associated with donating an organ while living with HIV is unknown

14.4.E Living Donor Exclusion Criteria

Table 14-10: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.
	
	Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:
	• Is both less than 18 years old and mentally incapable of making an informed decision
	• Living with HIV, and
	    o the living donor is donating a non-kidney or non-liver organ, and
	    o ~~unless~~ the requirements for a variance are not met, according *to Policy 15.7.D: Open Variance for the Recovery and Transplantation of Organs from ~~HIV Positive~~ Donors with HIV*
	• Active malignancy, or incompletely treated malignancy that either
	    o requires treatment other than surveillance or
	    o has more than minimal known risk of transmission
	• High suspicion of donor inducement, coercion, or other undue pressure
	• High suspicion of knowingly and unlawfully acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ
	• Evidence of acute symptomatic infection (until resolved)
	• Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

Additional Exclusion Criteria for Living Kidney Donors	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria:
	• Uncontrollable hypertension or history of hypertension with evidence of end organ damage
	• Type 1 diabetes
	• Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals either
	    o evidence of end organ damage or
	    o unacceptable lifetime risk of complications

Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

15.2 Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements

Transplant candidates must be tested for:

1. HIV using a CDC recommended laboratory HIV testing algorithm
2. Hepatitis B surface antigen (HBsAg)
3. Hepatitis B core antibody (total anti-HBc)
4. Hepatitis B surface antibody (HBsAb)
5. Hepatitis C antibody (anti-HCV)
6. Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)

unless the testing would violate state or federal laws.
Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests.

For all candidates 12 years or older, candidate samples must be drawn during the hospital admission for transplant but prior to anastomosis of the first organ.

If the candidate is known to be ~~infected~~ <u>living</u> with HIV, HBV, or HCV, then testing for the known viral infection or infections is not required, however the other tests required according to this policy must still be performed.

Candidates who test positive for HIV, hepatitis B, or hepatitis C must be offered appropriate counseling.

As part of the candidate's medical evaluation, an assessment for the need to provide HBV vaccination must occur. The transplant program must report the candidate's HBV vaccination status to the OPTN. If the transplant program determines that vaccination cannot be initiated or completed due to timing related to transplant, medical contraindication, or other reasons in the transplant program's medical judgement, the reason for not initiating or completing HBV vaccination must be documented in the candidate's medical records and reported to the OPTN.

~~The OPTN permits HIV test positive individuals as organ candidates if permitted by the transplant hospital. Care of HIV test positive organ candidate and recipients must not deviate from general medical practice.~~

15.3.B Donors with Risk Identified Pre-Transplant

Transplant programs must meet the requirements according to *Table 15-1* below when the deceased or living donor has risk of disease transmission identified pre-transplant.

Table 15-1: Requirements for Donors with Risk Identified Pre-Transplant

Each time any of the following occurs:	Then transplant programs must do *all* of the following:
• The donor tests positive for *any* of the following: a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT	1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 2. Document this consent in the intended recipient's medical record 3. Follow the recipient for the development of potential donor-derived disease after transplant
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the organ offered is a kidney, liver, or liver-kidney	1. A transplant physician must confirm that the candidate is living with HIV. 2. A transplant physician must explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant ~~hospital~~ program participates in an approved variance according to *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from ~~HIV-positive~~ Donors with HIV*	1. Confirm that the candidate is living with HIV. 2. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record
• The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*	1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor 2. Document that this information was provided in the intended recipient's medical record

15.7 ~~Open Variance for the~~ Recovery and Transplantation of Organs from ~~HIV-positive~~ Donors with HIV

~~This variance applies to transplant hospitals participating in an institutional review board (IRB) approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV-positive recipients, including Health and Human Services (HHS) research criteria pertaining to transplantation of organs from HIV-positive donors, as applicable.~~

~~Transplant hospitals participating in this variance must submit *all* of the following to the OPTN:~~

- ~~A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria.~~
- ~~IRB data safety monitoring reports at each deadline in the schedule.~~

15.7.A Requirements for Allocating ~~HIV-positive Deceased Donor~~ Organs from Deceased Donors with HIV

~~In addition to the requirements of the OPTN Final Rule, t~~The OPO may allocate ~~HIV-positive~~ organs from deceased donors with HIV only after determining the following:

1. That the potential deceased donor has been tested according to *Policy 2.9: Required Deceased Donor Infectious Testing* and has ~~is~~ HIV~~-positive;~~ and
2. That the ~~HIV-positive~~ candidate is living with HIV ~~is~~ and willing to accept an ~~HIV-positive~~ organ from a donor with HIV.
3. For non-kidney and non-liver candidates living with HIV, that the candidate must be willing to accept the organ as part of an IRB-approved research protocol that meets the requirements in the National Institutes of Health (NIH) Final Notice regarding the recovery and transplantation of organs from donors with HIV and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

The OPO must only allocate ~~HIV-positive~~ organs from donors with HIV to ~~HIV-positive~~ candidates living with HIV appearing on the match run, except in cases of directed donation. The OPO must verify that the potential recipient is ~~registered as~~ a ~~HIV-positive~~ candidate living with HIV who is registered at a transplant ~~hospital~~ program that meets the requirements in *Policy 15.7.~~C~~B: Transplant ~~Hospital~~ Program Requirements for Transplantation of ~~HIV-positive~~ Organs from Donors with HIV*.

15.7.~~C~~B Transplant ~~Hospital~~ Program Requirements for Transplantation of ~~HIV-positive~~ Organs from Donors with HIV

The transplant program must meet the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk.*

In order for a ~~HIV positive~~ candidate living with HIV to appear on a deceased donor match run for an organ from a ~~HIV positive~~ donor with HIV, the transplant program must complete a two-person reporting and verification process. This process must include two different individuals who each make an independent report to the OPTN that the candidate is living with HIV and willing to accept an organ from a donor with HIV.

For kidney, liver, and liver-kidney candidates, a transplant physician must verify and document in the medical record that the candidate is living with HIV and willing to accept an organ from a donor with HIV. This must occur prior to the two-person reporting and verification process.

For non-kidney and non-liver candidates, the candidate must be willing to accept an organ from a donor with HIV as part of an IRB-approved research protocol that meets the requirements in the NIH Final Notice and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

15.7.C~~B~~ Recovery Hospital Requirements for Transplantation of ~~Allocating~~ ~~HIV-positive~~ ~~Living Donor~~ Organs from Living Donors with HIV

~~In addition to the requirements of the OPTN Final Rule, t~~The recovery hospital must confirm that the potential living donor is living with HIV ~~HIV-positive~~ and the candidate ~~potential recipient~~ is living with HIV and willing to accept an ~~HIV-positive~~ organ from a living donor with HIV ~~as part of a research protocol~~.

For non-kidney and non-liver living donors with HIV, the recovery hospital must confirm that the candidate is willing to accept an organ from a living donor with HIV as part of an IRB-approved research protocol that meets the requirements in the NIH Final Notice and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

15.7.D Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV

This variance applies to transplant programs participating in an institutional review board (IRB) approved research protocol regarding the recovery of non-kidney and non-liver organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into candidates living with HIV.

~~In addition to the requirements of the OPTN Final Rule, t~~Transplant ~~hospitals~~ programs may transplant ~~HIV positive~~ non-kidney and non-liver organs from donors with HIV only if *all* of the following are true:

1. The transplant ~~hospital~~ program notifies and provides documentation to the OPTN that it is participating in an ~~institutional review board~~ IRB-approved research protocol that meets the requirements in the ~~OPTN~~ NIH Final Notice ~~Rule~~ regarding the research criteria for recovery and transplantation of non-kidney and non-liver organs from ~~HIV-positive~~ ~~individuals~~ donors with HIV.[61]

[61] A crosswalk in the HHS NIH Final Rule identifies the specific research criteria that programs must meet: Federal Register :: Final Revised Human Immunodeficiency Virus (HIV) Organ Policy Equity Act Safeguards and Research Criteria for Transplantation of Organs From Donors With HIV.

2. The transplant ~~hospital~~ program obtains informed consent from the potential transplant recipient to participate in the ~~institutional review board~~ IRB-approved protocol that meets research criteria requirements described in the ~~OPTN~~ NIH Final Notice ~~Rule~~.
3. The transplant ~~hospital~~ program meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk.*

The OPTN has the authority to collect data safety monitoring reports from transplant programs participating in this variance upon request.

Transplant ~~hospitals~~ programs must notify the OPTN of when protocols will be renewed and if ~~it is~~ they will no longer participating in an IRB-approved research protocol that meets the requirements in the ~~OPTN~~ NIH Final Notice ~~Rule~~ regarding the recovery and transplantation of non-kidney and non-liver organs from ~~HIV-positive~~ ~~individuals~~ donors with HIV.

The OPTN may release to the public the names of transplant ~~hospitals~~ programs participating in this variance.

16.6.A Extra Vessels Use and Sharing

Extra vessels must only be used for organ transplantation or modification of an organ transplant.

Transplant hospitals may share deceased donor extra vessels with other transplant hospitals, unless storage is prohibited by Policy 16.6.B: Extra Vessels Storage. Extra vessels from a living donor must only be used for transplant or modification of an organ transplant for the original intended recipient and must not be shared. Extra vessels from a ~~HIV-positive~~ donor with HIV must only be used for transplant for the original intended recipient.

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