

## Briefing Paper

# Modify HOPE Act Variance to Include Other Organs

*OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC)*

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# Modify HOPE Act Variance to Include Other Organs

*Affected Policies:* 5.3.B: Infectious Disease Screening Criteria, 5.4.E: Allocation to Candidates Not on the Match Run, 5.5.C: OPO Requirements for Positive HIV Results, 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 Committee (DTAC)  
*Public Comment Period:* January 22, 2019 – March 22, 2019

## Executive Summary

The HIV Organ Policy Equity Act was enacted on November 21, 2013, permitting use of organs from HIV-positive donors for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants.<sup>1</sup> In November 2015, OPTN policies for recovery and transplantation of HIV positive livers and kidneys to HIV-positive candidates were effective,<sup>2</sup> in addition to final research requirements for program participation, published by the National Institutes of Health (NIH).<sup>3</sup>

This proposal modifies the policies enacted by the OPTN HOPE Act Variance to allow programs meeting the research and experience requirements to recover and transplant organs in addition to liver and kidney. Program participation requirements, including meeting minimum experience, operating under an approved Institutional Review Board (IRB), and adhering to the federal research protocol guidelines, remain unchanged.

No clinical outcomes that may threaten the safety of such transplants have been reported to the OPTN since 2015. Expansion of the variance to include other organs besides kidney and liver has been requested by active program participants. Federal criteria do not limit the program to specific organ transplants, and explicitly encouraged future expansion of the program upon publishing research study participation criteria in November 2015.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

Yes, the Ad Hoc Disease Transmission Committee (hereafter, “the Committee”) requests feedback from the community about this proposal to expand the availability of HIV positive organs evaluated and potentially recovered, beyond liver and kidney.

Members are asked to comment on both the immediate and long-term impact on budgets and other resources that may be required if this proposal is approved. Additional impact on outcomes monitoring, or

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<sup>1</sup> HIV Organ Policy Equity Act, 113-51 (11/21/2013).

<sup>2</sup> Changes to HOPE Act Open Variance. OPTN Board Briefing Paper (6/2016).

<sup>3</sup> Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. Federal Register, Vol. 80, No. 227. 25 Nov, 2015. <https://www.gpo.gov/fdsys/pkg/FR-2015-11-25/pdf/2015-30172.pdf> (accessed 11/29/2018).

organ procurement is also requested. This information assists the Board in considering the proposal and its impact on the community.

## What problem will this proposal address?

This proposal expands the OPTN HOPE Act Policy Variance, enacted on November 21, 2015, to include organs beyond kidney and liver, while ensuring that broader use of these organs is consistent with the federal legal statute.

The federal HOPE Act, originally passed in 2013, allows organ transplantation from HIV positive donors to HIV positive candidates at transplant programs that meet and follow research protocol guidelines established by the National Institutes of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH).<sup>4</sup>The law requires that transplant programs must operate under an approved Institutional Review Board (IRB) protocol.

The OPTN established a HOPE Act policy variance on November 21, 2015, to reflect these changes in federal organ transplantation requirements, allowing HIV positive donor organs into HIV positive recipients for kidney and liver transplants only.<sup>5</sup> OPTN policy requires transplant programs to submit applications and be approved to participate in the HOPE Act variance.<sup>6</sup> This includes submission of safety data to the OPTN on the same schedule as they are provided to the transplant program's IRB.

As of April 16, 2019, there are 53 kidney and liver programs (47 deceased donor and 6 living donor) among 31 centers approved for participation in the HOPE Act Variance. As of the same date, there have been 120 transplants (85 kidney (including 1 en bloc kidney and 1 living donor), 35 liver) performed among 16 approved programs under the HOPE Act Variance. Recovery of these organs has increased the number of organs available for candidates on the kidney and liver waitlists. To date, OPTN data suggests little difference in outcomes in comparing HIV positive recipient data and non-HIV positive recipient data. While this data is based on short-term outcomes, there have been no data that would preclude HOPE Act research from continuing.

The HOPE Act federal legislation was written broadly to apply to transplants besides kidney and liver. The criteria developed by NIAID specified kidney and liver to be included in its research, but indicated future expansion of the study. OPTN programming limited the variance to kidney and liver transplants, but now members indicate interest to expand.<sup>7</sup> The transplant programs would still be subject to the established federal HOPE Act requirements, including following NIAID research guidelines, as well as OPTN policy requirements under the variance.

Candidates would have to meet the medical criteria in the NIH guidelines, and their transplant programs would also have to be approved to participate in the variance and meet the program experience requirements of the NIH guidelines for each individual organ. Only programs with previous experience, as outlined in the criteria, transplanting HIV negative organs to HIV positive recipients could expand, in order to ensure patient safety and to comply with NIH requirements.<sup>8</sup>

Changing OPTN policy with this proposal to allow for broader use of HIV positive donor organs will be consistent with the federal legal statute.

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<sup>4</sup> HIV Organ Policy Equity Act, 113-51 (11/21/2013).

<sup>5</sup> Changes to HOPE Act Open Variance. OPTN Board Briefing Paper (6/2016).

<sup>6</sup> OPTN Policies. 1.3C Joining an Open Variance.

<sup>7</sup> Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. Federal Register, Vol. 80, No. 227. 25 Nov, 2015. <https://www.gpo.gov/fdsys/pkg/FR-2015-11-25/pdf/2015-30172.pdf> (accessed 11/29/2018)

<sup>8</sup> *Ibid*

## Why should you support this proposal?

This change may help increase the number of transplants, reduce organs currently discarded or not procured, and help HIV positive candidates, often a medically underserved and vulnerable population, have increased access to transplant.<sup>9</sup> Additionally, results from an NIAID-funded study of 275 people with HIV who received a kidney or liver from an uninfected donor showed that outcomes and survival rates were similar to those of transplant recipients without HIV.<sup>10</sup>

Since no reported clinical outcomes that may threaten the safety of such transplants have been reported since the OPTN began the variance program in 2015, expanding the OPTN variance to include other organs besides kidney and liver is proposed. The community feels that because evidence indicates it is safe to transplant kidney and livers from HIV positive donors to HIV positive recipients, then it is likely safe to expand these types of transplants to other organs.

The NIH criteria was written broadly to apply to transplants besides kidney and liver. The research criteria developed by the National Institutes of Health (NIH) that all approved HOPE Act programs must follow *“focuses on liver and kidney transplantation, as it is only in liver and kidney transplantation that there is substantial experience with transplantation from HIV negative donors to HIV positive recipients. The intent is not to exclude the possibility of HIV positive to HIV positive transplantation of other organs such as heart or lung in the future; however, transplant teams should gain experience with HIV negative to HIV positive transplantation of a specific organ before taking on the more complex and less well-defined issues of HIV positive to HIV positive transplantation of that organ.”*<sup>11</sup>

This proposal additionally fulfills the OPTN's requirement under the HOPE Act to review the results of the scientific research *“to determine whether the results warrant revision of the standards of quality.”*<sup>12</sup> The OPTN must work with HOPE Act researchers to monitor the safety of the transplants performed as part of the research studies. This proposal requires researchers to submit periodic data safety monitoring board reports to the OPTN, as required by the HOPE Act Variance implemented in 2015 by the OPTN, for any HIV positive organ transplants, not limited to kidney and liver. This will allow OPTN staff to identify issues or trends across multiple research studies and proactively address potential problems. The HOPE Act variance is currently in effect through January 1, 2020, at which time federal program requirements to participate will be reviewed by the Secretary of Health and Human Service (HHS).

## How was this proposal developed?

The HOPE Act variance, to allow HIV positive donor organs to be transplanted into HIV positive recipients for liver and kidney, has been in effect for approximately three years (as of 11/21/2015). The OPTN began to receive requests from the active HIV transplant community to expand this variance beyond liver and kidney, as approved programs began to participate. As of 11/23/2018, 45 programs across 27 centers participate in the HOPE Act variance.

The Ad Hoc Disease Transmission Advisory Committee (DTAC) decided that it was appropriate to consider expanding the variance and began to discuss in July 2018, sponsorship of a policy change to allow additional organs to be included. With overwhelming support, the Committee proposed to include additional organs, with the already established experience and research requirements to programs in order to participate:

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<sup>9</sup> *Organs from deceased donors with false-positive HIV screening tests: An unexpected benefit of the HOPE act.* American Society of Transplantation. 18 June, 2018.

<sup>10</sup> *NIH Publishes Criteria for Research on Organ Transplantation Between People with HIV Infection.* National Institute of Allergy and Infectious Diseases. 25 November 2015. <https://www.niaid.nih.gov/news-events/nih-publishes-criteria-research-organ-transplantation-between-people-hiv-infection>. (accessed 11/29/2018)

<sup>11</sup> *Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV.* Federal Register, Vol. 80, No. 227. 25 Nov, 2015. <https://www.gpo.gov/fdsys/pkg/FR-2015-11-25/pdf/2015-30172.pdf> (accessed 11/29/2018)

<sup>12</sup> *HIV Organ Policy Equity Act, 113-51 (11/21/2013).*

1. Request and approval to the OPTN Contractor to participate, as required in *Policy 1.3.B: Application for a Variance*
2. Adherence to the required submission of IRB data safety monitoring reports and requirements to meet the NIH research criteria in *Policy 1.3.D: Reporting Requirements for Variances*

OPTN staff discussed the OPTN's role in reviewing the results of scientific research as outlined in the HOPE Act. The OPTN will continue to review results of HOPE Act research as well as OPTN/ data to determine if additional policy changes are warranted.

The Committee and staff considered how to accommodate VCA transplants, as the proposed modified policy language is inclusive of all organs. VCA transplants are allocated with a separate match run from all other organs. The VCA match-run is manual and maintained by the UNOS Organ Center, while the electronic match-run is the allocation method for all other organs. The UNOS Organ Center does not currently have a process in place to adhere to the required two-person reporting and verification process.<sup>13</sup>

Should hospitals with the qualifying experience to participate in the research study and perform VCA transplants under the HOPE Act be approved, the UNOS Organ Center will develop a way to create the two-person reporting and verification process. Since all VCA transplants are rare, there may not be programs that meet the experience requirements currently.<sup>14</sup> The OPTN will monitor VCA programs performing transplants to HIV positive recipients.

Requirements to participate and submit data for research to the OPTN Contractor remain in effect through January 1, 2020. Continued submission of data will allow the OPTN to identify issues or trends across multiple research studies and proactively address potential problems. Program expansion will be permitted only for those applying programs that have previous experience transplanting HIV negative donor organs to HIV positive recipients, as required by the NIH criteria.

Feedback from stakeholder organizations identified by the Committee was requested during the development of the proposal. Some comments of support for the proposal, but none in opposition have been received. The organizations included:

- American Pancreatic Association
- American Public Health Association
- American Society for Reproductive Medicine (ASRM)
- American Society of Reconstructive Transplant (ASRT)
- American Society of Transplantation (AST)
- American Society Transplant Surgeons (ASTS)
- American Thoracic Society
- Association of Organ Procurement Organizations (AOPO)
- HIV Medicine Association (HIVMA)
- International Pancreas & Islet Transplant Association (IPITA)
- International Society for Heart and Lung Transplantation (ISHLT)
- International Society for Vascularized Composite Allograft (ISVCA)
- Transplant Infectious Disease (TID)
- HIV Medicine Association (HIVMA)
- Infectious Diseases Society of American (IDSA)

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<sup>13</sup> OPTN Policies. 15.7C Transplant Hospital Requirements for Transplantation of HIV Positive Organs

<sup>14</sup> NIH Publishes Criteria for Research on Organ Transplantation Between People with HIV Infection. National Institute of Allergy and Infectious Diseases. 25 November 2015. <https://www.niaid.nih.gov/news-events/nih-publishes-criteria-research-organ-transplantation-between-people-hiv-infection>. (accessed 11/29/2018)

## How well does this proposal address the problem statement?

Expansion of the HOPE Act variance will allow for a greater number of potential HIV positive donor organs to be available for candidates on the waitlist. Because more organs are available for transplant, more candidates can receive transplants. While transplantation of these organs continues to be conducted as research, clinical outcomes have not been reported that would prevent expansion of the variance based on safety concerns.<sup>15</sup>

Including additional organs in the HOPE Act variance should allow for greater transplant access to the HIV positive population. In 2017, there were 19 transplants (12 kidney and 7 liver) under the HOPE Act variance, compared to 19,849 kidney and 8,082 liver transplants (deceased and living transplants total) overall. While transplants under the HOPE Act variance represent less than one percent of all transplants in 2017, this proposal allows the program to contribute to a greater percentage of HIV positive transplants to annual overall transplants.

The proposal also ensures that data submission requirements, despite expansion of variance, remain for transplant programs participating in the HOPE Act variance. The OPTN Contractor will continue to monitor the research studies to ensure patient safety and fulfill the data submission requirements in Policy 1.3.D: *Reporting Requirements for Variances*.

## Was this proposal changed in response to public comment?

No, this proposal was not amended following the January 22, 2019-March 22, 2019 public comment period.

The proposal passed on the consent agenda in all eleven regions with no additional comments. Several OPTN Committees, including the Transplant Coordinators Committee, Thoracic Committee, and Patient Affairs Committee (PAC), commented in support of the proposal. The PAC emphasized that HIV-positive recipients must also have equal access to non-HIV positive donors. The PAC also requested future guidance for HIV positive living donors, and greater collaboration with patient advocacy groups.

Transplant-affiliated organizations commenting in support of the proposal include the American Society of Transplantation (AST), International Society for Heart and Lung Transplantation (ISHLT), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Thoracic Surgeons (STS), American Nephrology Nurses Association (ANNA), and the HOPE in Action Multicenter Consortium. While strong support of expanding the HOPE Act policy to include additional organs is evident through public comment, the importance of continual review of policies and practices to ensure safe utilization of organs is also emphasized. Continued collection of data to inform future clinical decisions is reaffirmed. The HOPE in Action Multicenter Consortium requests additional guidance regarding the experience requirement for combined kidney-pancreas transplant, as well, which the Committee refers for NIH direction.

The OPTN website, containing the Frequently Asked Questions (FAQ) associated with the HOPE Act, will be updated pending Board approval of this proposal.

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<sup>15</sup> These outcomes may include unintended or preventable disease transmission, incidence of opportunistic infections, AIDS defining diagnoses, or higher than expected delayed graft function, rejection, or other post-transplant complications.

The Committee reviewed all public comments and made no edits. The Committee voted (16 – in favor, 0 – opposed) to send the proposal to the OPTN Board of Directors for consideration at the June 2019 meeting.

## Which populations are impacted by this proposal?

This proposal will impact all transplant programs, not only those currently participating in the HOPE Act variance in transplantation of kidney and liver. If a greater number of HIV positive organs become available and transplanted, decreased waiting times are possible for all candidates. The OPTN does not collect the HIV status of candidates on the waiting list, therefore the number of potential candidates that would benefit from the expansion is not available.

HIV positive candidates are typically an underserved and vulnerable population, experiencing longer waiting times. Data show that HIV positive candidate are often part of other vulnerable populations such as, but not limited to, minorities, LGBT, economically disadvantaged populations. Expansion of the HOPE Act would provide more transplants to this group.

The proposal will also affect HIV positive transplant candidates and HIV positive recipients participating in the HOPE Act variance by allowing the OPTN to identify issues or trends across multiple research studies and identify potential patient safety concerns

## How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* This proposal supports the goal by allowing HIV positive recipients to accept organs, beyond liver and kidney, from HIV positive donors, thus increasing the pool of organs available for transplant.
2. *Improve equity in access to transplants:* HIV positive candidates can be at higher risk than non HIV positive candidates for developing end-stage liver and kidney disease. Increasing the availability of organs to this group may increase equity to this vulnerable population.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Decreased waiting time to transplant for all candidates can result.
4. *Promote living donor and transplant recipient safety:* No expected impact on this goal.
5. *Promote the efficient management of the OPTN:* No expected impact on this goal.

## What are the potential costs associated with this proposal?

### Member:

Programs must be approved by the OPTN to transplant HIV positive recipient organs from HIV positive donors, in addition to participating in research required by the National Institutes of Health (NIH). Cost to transplant programs to create separate protocol and collect and submit separate data for each additional organ added can be costly. Data are submitted to an institutional review board (IRB) before being sent to the OPTN.

Staff time and effort to develop protocol, collect data, and work with an IRB will substantially increase with each additional program. Patient care pre, during, and post- transplant may be longer and more costly due to extra testing, treatment, and complications that may be needed for HIV positive recipients. OPO fees per transplant may increase due to additional care.

Variables that may affect costs include ease of work, IRB schedules, and fee charges from the IRB. Ability to obtain reimbursement from payers for unexpected complications or length of stay for HOPE Act recipients is uncertain.

Increase in volume of transplants at HOPE Act approved programs may help to offset some additional costs. The average wait time for HIV positive recipients receiving transplants may decrease nationally, and the number of total transplants overall may increase.

Implementation is estimated at 3-6 months per additional HOPE Act program to develop protocol and to train and education staff at transplant hospitals.

## **UNOS:**

The IT department estimates just under 2,000 hours (Large Effort) to modify UNet™ to allow additional HIV positive donor organs to be transplanted into HIV positive recipients. Member Quality receives HOPE Act variance member applications and expects an increase in applications and management of approved programs. Both the IT and Research departments expect over 100 hours each to monitor approved programs and transplant outcomes.

## **How will the OPTN implement this proposal?**

The OPTN application for members to join the open variance must be modified to include information in this proposal. The OPTN will continue to review the data safety monitoring reports from institutional review board approved studies, as well as outcomes based on standard recipient data collected by the OPTN.

This proposal will require OPTN Contractor changes to:

1. Allow for candidates other than kidney and liver to indicate their willingness to accept an HIV positive organ in Waitlist if listed at transplant programs approved by the OPTN under the HOPE Act variance to transplant HIV positive organs. A second person will need to verify the candidate's willingness to accept an HIV positive organ.
2. Allow HIV positive donor to HIV positive recipient matches in organs other than kidney and liver if all other OPTN policy requirements are met regarding the HOPE Act variance.

The programming for this proposal will be a large effort.

## **How will members implement this proposal?**

Transplant hospitals that meet the required experience in non-HIV to HIV positive transplantation interested in participating in a HOPE Act IRB approved research study must provide the OPTN with a schedule of deadlines for data safety monitoring reports and provide reports to the OPTN according to the schedule. IRB-approved research protocols specific to additional organs must be developed.

OPOs will be able to expand the pool of organs evaluated and potentially recovered. This will require protocol modification and staff training.

## **Will this proposal require members to submit additional data?**

Yes, members participating in the HOPE Act variance expansion will be required to submit IRB data safety monitoring reports for each transplant, as already required, if participating in the variance, to the OPTN to allow for ongoing review of research studies to ensure patient safety. Collecting data for this



purpose is consistent with the OPTN Principles of Data Collection, in that it captures data about HIV populations as required by the federal research criteria published in November 2015.<sup>16</sup>

## How will members be evaluated for compliance with this proposal?

Members will be expected to comply with the requirements in the proposed language. In addition to the monitoring described below, all policy requirements and data entered in OPTN Contractor software may be subject to OPTN review, and members are required to provide documentation as requested.

This proposal will not change the current routine monitoring of members. OPTN Contractor staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy. Staff will also continue to review the reported disposition of extra vessels to verify that the use, storage, and sharing of extra vessels has occurred according to OPTN policy. Staff will continue to investigate potential policy violations identified through these reviews.

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The OPTN has a statutory requirement to review the results of HOPE Act research studies. In order to “review the results of scientific research to determine whether the results warrant revision of the standards of quality,” the OPTN will review:

- The OPTN database.
- Published peer-review literature.
- OPTN data and Data Safety Monitoring Board reports from IRBs reviewing protocols including, but not limited to, reported patient safety events and unexpected disease transmissions.

Additionally, using the OPTN database, this policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- Has the number of HOPE Act transplants increased?
- Has the number of HIV+ donors recovered for transplant increased?
- Which organs are most commonly transplanted under the HOPE Act variance?
- Has the number of programs participating in the HOPE Act variance increased?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this variance:

- The number of HOPE Act transplants, overall, and by transplanted organ
- Number of centers approved for participation in the HOPE Act variance by organ
- Number of HIV+ donors (as reported through the OPTN HIV serology tests) recovered
- Number of transplanted organs allocated via the HOPE Act, overall and by organ

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<sup>16</sup> *NIH Publishes Criteria for Research on Organ Transplantation Between People with HIV Infection*. National Institute of Allergy and Infectious Diseases. 25 November 2015. <https://www.niaid.nih.gov/news-events/nih-publishes-criteria-research-organ-transplantation-between-people-hiv-infection>. (accessed 11/29/2018)

## Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

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### 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
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	<u>Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas</u> <del>Kidney, Liver;</del> Use of HIV positive donor organs is only permissible for kidney and liver transplantation at this time.

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### 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:

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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

- 28 • Donor HLA and candidate's unacceptable antigens
- 29 • Donor height
- 30 • Donor weight
- 31 • Infectious disease test results
- 32 • For HIV positive deceased donors ~~kidneys and livers~~, the OPO and transplant hospital
- 33 must also do *both* of the following:
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- 35 a. Verify that the potential recipient is registered as a HIV positive candidate at a
- 36 transplant hospital that meets the requirements in *Policy 15.7.C Transplant Hospital*
- 37 *Requirements for Transplantation of HIV Positive Organs*
- 38 b. Meet the requirements in *Policy 15.7: Open Variance for the Recovery and*
- 39 *Transplantation of Organs from HIV Positive Donors*

40 The transplant hospital must maintain all related documentation.

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### 42 **5.5.C OPO Requirements for Positive HIV Results**

43 If a donor is found to be positive for HIV after any match run has been executed, the host OPO  
44 must report the updated information to the OPTN Contractor and do *all* of the following for each  
45 organ being allocated:

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- 47 1. Stop allocation on the original match run for this donor
- 48 2. Re-execute match runs in order to include *only* HIV-positive candidates participating in an
- 49 institutional review board approved research protocol that meets the requirements in the Final
- 50 Rule regarding the recovery of organs from individuals known to be infected with HIV
- 51 according to *Policy 15.7.A: Requirements for Allocating HIV Positive Deceased Donor*
- 52 *Organs*
- 53 3. Withdraw any pending offers to candidates who are not HIV positive *and* also participating in
- 54 an institutional review board approved research protocol that meets the requirements in the
- 55 OPTN Final Rule according to *Policy 15.7.C: Transplant Hospital Requirements for*
- 56 *Transplantation of HIV Positive Organs*
- 57 4. Continue allocating organs using the re-executed match run. Only recover and send extra
- 58 vessels from this donor with an organ allocated from this donor.
- 59 ~~Allocate only kidneys and livers from HIV positive donors. Extra vessels from these donors must~~
- 60 ~~only be allocated with the kidneys or liver and must only be used for transplantation of these~~
- 61 ~~organs. Members must not share or store extra vessels from HIV positive donors.~~
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### 63 **15.7.C Transplant Hospital Requirements for Transplantation**

### 64 **of HIV Positive Organs**

65 In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant HIV  
66 positive organs only if *all* of the following conditions are true:

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- 68 1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is
- 69 participating in an institutional review board approved research protocol that meets the
- 70 requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from
- 71 HIV positive individuals.
- 72 2. The transplant hospital obtains informed consent from the potential transplant recipient to
- 73 participate in the institutional review board protocol that meets requirements in the OPTN Final
- 74 Rule.
- 75 3. The transplant hospital meets the informed consent requirements according to *Policy 15.3*
- 76 *Informed Consent of Transmissible Disease Risk.*
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78 In order for an HIV positive candidate to appear on a match run for an organ from a HIV positive  
79 donor~~kidneys or livers~~, the transplant hospital must complete a two-person reporting and

80 verification process. This process must include two different individuals who each make an  
81 independent report to the OPTN Contractor that the candidate is willing to accept an HIV positive  
82 organ as part of a research protocol.

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84 Transplant hospitals must notify the OPTN Contractor if it is no longer participating in an IRB  
85 approved research protocol that meets the requirements in the OPTN Final Rule regarding the  
86 recovery and transplantation of organs from HIV positive individuals.

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88 The OPTN Contractor may release to the public the names of members participating in this  
89 variance.  
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## 91 **16.6 Extra Vessels Transplant and Storage**

### 92 **16.6.A Extra Vessels Use and Sharing**

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

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