

At-a-Glance

Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

- **Affected Policies:** 2.7.A (Exceptions to HIV Screening Requirement), 5.3.C (Liver Acceptance Criteria), 5.4.B (Order of Allocation), 5.4.F (Allocation to Candidates Not on the Match Run), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.E (Living Donor Exclusion Criteria), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.A (Transplant Program Requirements), 15.5 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), 16.7.B (Vessel Recovery, Transplant, and Storage), 16.7.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), and 16.7.E (Blood Type Verification Prior to Transplant of Living Donor Vessels).
- **Organ Procurement Organization Committee**

Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to continue to amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).
- **Affected Groups**
 - Directors of Organ Procurement
 - Lab Directors/Supervisors
 - OPO Executive Directors
 - OPO Medical Directors
 - OPO Coordinators
 - Transplant Administrators
 - Transplant Data Coordinators
 - Transplant Physicians/Surgeons
 - PR/Public Education Staff
 - Transplant Program Directors
 - Transplant Social Workers
 - Organ Recipients
 - HIV Positive Candidates
 - Organ Candidates
 - Living Donors
 - HIV Positive Donors
 - Donor Family Members
 - General Public
- **Number of Potential Candidates Affected**

Over the past several years, there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al determined that annually there are as many as 500-600 potential HIV positive

deceased donors that could result in several hundred additional kidney and liver transplants each year.¹

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal supports the OPTN's Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

- **Specific Requests for Comment**

1. The Committee is requesting input from the transplant community regarding the inclusion of living donors in the research study.
2. The Committee is requesting input on how to handle directed donations from deceased donors when the intended recipient does not appear on the match run based on ABO. The Committee is proposing that HIV positive organs only be allocated to recipients that appear on the match run but understand that this could negatively impact directed donations.

¹ Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. *American Journal of Transplantation*, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

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Organ Procurement Organization Committee

Public comment response period: January 27, 2015 – March 27, 2015

Summary and Goals of the Proposal:

Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to continue to amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

Background and Significance of the Proposal:

The HOPE Act outlines future changes to the Final Rule and contains a schedule of deliverable deadlines. The initial requirements are:

- By November 21, 2015, the Secretary of HHS must develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ.
- By November 21, 2015, the Secretary of HHS must revise the section of the OPTN Final Rule² (42 CFR 121.6) that presently requires the OPTN to adopt and use standards to prevent the recovery of HIV-infected organs.
- By November 21, 2015, to the extent determined by the Secretary to be necessary to allow the conduct of research, the OPTN shall revise standards of quality (i.e. policies) for acquisition and transportation of donated organs infected with HIV in accordance with the criteria developed by the Secretary as described above. This must begin concurrently with the Secretary's development of criteria for research in order to meet the two year deadline.

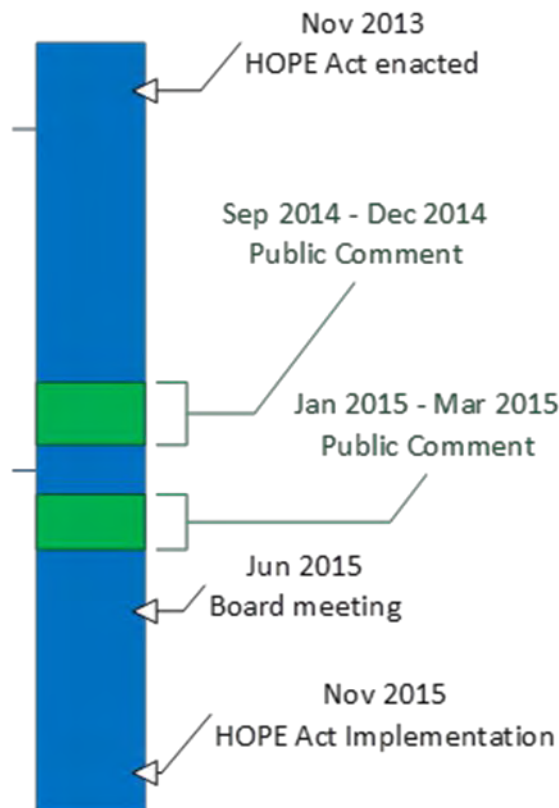
By November 21, 2017, and each year thereafter the Secretary of HHS will:

- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards;
- Determine if participation in clinical research, as a requirement for such transplants, is no longer warranted;

² <http://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/>

- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards of quality 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;
- Determine necessary conduct of research in accordance with the criteria developed;
- Determine if results warrant revision of the standards of quality; and
- Direct the OPTN to revise such OPTN standards in a way that ensures the changes will not reduce the safety of organ transplantation.

OPOs will remain responsible for “arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)” per 42 USC 273(b)(3)(C).



Formation of a joint work group

The OPTN formed a joint work group with representation from the Organ Procurement Organization (OPO) Committee, Operations and Safety Committee, Ad Hoc Disease Transmission Advisory Committee (DTAC), Scientific Registry of Transplant Recipients (SRTR), and Health Resources and Services Administration (HRSA). This work group has been meeting on a regular basis to identify necessary policy changes and discuss future operational and programming issues.

Initial proposal

The intent of the initial proposal was to provide notice to the transplant community about the upcoming changes to OPTN policies and the Final Rule that will allow for the conduct of research relating to the recovery and transplantation of organs from donors infected with HIV into individuals who are known to be infected with HIV prior to receiving the organ. The proposal has been supported by all regions, OPTN Committees, individuals, and professional organizations. There was some concern raised by the Kidney Transplantation Committee and the American Society of Transplantation, especially regarding the inclusion of living donors.

Kidney Transplantation Committee - The Committee had several questions about the implications of the HOPE Act and changes to OPTN policy to implement it. The Committee requests that the OPO Committee continue to update the Kidney Committee on whether these changes will apply to living donors. There was some disagreement among the Committee about whether application to living donors would be a positive or negative change. Some members voiced the opinion that most transplant programs probably shouldn't and likely wouldn't consider an HIV positive living donor while others thought that there might be a high percentage of people in this category who might be willing to donate to an HIV positive candidate. The Committee does have concern about how outcomes of these transplants will be evaluated by the Membership and Professional Standards Committee and the SRTR. The Committee feels that there should be some adjustment in the models considering this is part of an NIH approved research trial and the research protocol must be institutional review board (IRB) approved.

American Society of Transplantation - HIV infection is associated with a higher risk of intrinsic kidney disease. AST feels that including discussion of living donation is outside the intent of the act and should be reviewed more carefully before being included in a UNOS policy, regardless of the recommendations for research. Just as overt hypertension and diabetes are contraindications to living donation, HIV infection may have long term consequences to the health of a kidney donor.

OPTN Role

The work group discussed the OPTN's role in the research study. Overall, the work group agreed that current testing for infectious diseases provides the appropriate safeguards to prevent disease transmission. However, unlike current practice, organs from donors known to be infected with HIV will now be allocated and appropriate safeguards need to be in place to ensure that HIV-infected organs will be allocated using match runs that include only to those HIV-positive candidates willing to accept the organ as part of the research. The work group agreed that determination of donor and recipient eligibility, other than verifying HIV status, would be the responsibility of the researchers. The OPTN will require members to perform all the necessary testing, as they currently do, that will allow for screening of recipients.

Current proposal

The work group held monthly meetings from August to December 2014 to discuss operational issues and continue its review of policy. The work group continues to evaluate ways to provide the best protections for transplant patients and donors. The work group acknowledged that the OPTN and the transplant community have always focused on patient safety and preventing disease transmissions through organ transplantation, including HIV. However, since the recovery and transplantation of organs from HIV positive donors will be acceptable under the research study, there will be HIV positive organs recovered and allocated to HIV positive recipients. The

comprehensive review of OPTN policies has resulted in the proposed policy changes as described in the following sections of this proposal.

Liver Acceptance Criteria

Policy 5.3: *Liver Acceptance Criteria* deals with additional acceptance and screening criteria. Policy 5.3.C addresses liver acceptance such as mandatory reporting of acceptable deceased donor weight for each liver candidate. This section also includes a list of additional criteria that may be reporting including maximum number of mismatched antigens, blood types, segmental grafts, and several others. The work group agreed to include “willing to accept an HIV positive liver” if the candidate has agreed to accept such an organ as part of the research study.

Candidates Not Appearing on the Match Run

Policy 5.4.F: *Allocation to Candidates Not on the Match Run* currently allows this practice as long as the transplant hospital documents the reason and ensures the organ is safe and appropriate for the candidate. Acceptable reasons include directed donation or preventing organ wastage. While preventing the allocation of HIV positive organs to candidates not on the match run would serve as a safeguard for candidates, there was concern raised about the negative impact on directed donations. The work group will solicit input from the transplant community during the public comment period and determine the best approach to addressing this problem in order to prevent negative impacts on directed donations.

Living Donors and Kidney Paired Donation (KPD)

Although the HOPE Act does not specifically address living donation, OPTN policy development has proceeded with the assumption that living donors will be part of the final research protocols. While there has been some opposition raised, such as those mentioned earlier from the Kidney Transplantation Committee and the American Society of Transplantation, the timeline for making revisions to the OPTN policies is such that changes to the living donor policies are included in this proposal. With that in mind, the OPO Committee is interested in receiving feedback from the transplant community as outline in the “specific questions for comment” section of the at-a-glance box.

The proposed change to living donor policies is located in *Table 14-9: Living Donor Exclusion Criteria*, which will allow for an exception to the exclusionary criteria for HIV if qualifying under the research study.

The work group is not proposing any changes to the kidney paired donation policies at this time.

Informed Consent of Transmissible Disease Risk

Policy 15.3: *Informed Consent of Transmissible Disease Risk* addresses the requirement to obtain specific informed consent when there is an increased risk of transmissible disease or known medical condition that may be transmissible to the recipient. Since HIV positive organs will be transplanted as part of the research study, the work group agreed to delete the references to Policy 2.7: *HIV Screening of Potential Deceased Donors* since the prohibition on HIV positive organ recovery and transplant no longer resides in that policy. Additionally, since HIV will be a known condition transmitted as part of the research study, specific informed consent will be required.

Open Variance for the Recovery and Transplantation of HIV Positive Organs

During the initial proposal, the work group proposed a new section of policy to address the recovery and transplantation of HIV positive organs. The prohibition on these transplants has historically been in Policy 2.7: *HIV Screening of Potential Deceased Donors*. Since Policy 2 addresses deceased donor organ procurement, the work group agreed that Policy 15 was a more

logical place to address HIV positive transplants since it specifically addresses transmissible diseases and includes living and deceased donors. The initial proposal created a new section (15.3), however subsequent discussions lead to the decision to classify this proposed change as an open variance. This will make it clear that this is a time-limited study as described in the HOPE Act and allow the Board of Directors the flexibility to extend, amend, or terminate the variance at any time.

The open variance requires transplant centers to notify the OPTN contractor that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule. The information required in the notification will be determined once the final changes to the Final Rule are known. Only approved transplant centers will be allowed to indicate that HIV positive candidates on their waiting list are willing to accept an HIV positive organ as part of the research study. The transplant hospital must also obtain consent from potential transplant recipients to participate in the institutional review board protocol. The OPOs must confirm that the potential donor is HIV positive before releasing the organ to transplant hospital.

Infectious Disease Verification

The work group agreed that only transplant hospitals approved for the research study should be allowed to indicate that an HIV positive candidate is willing to accept an HIV positive donor. The work group also agreed that requiring a second verification of the potential candidate's willingness to accept an HIV positive organ would provide a good safeguard. Therefore, the proposed open variance policy will require two different individuals to report and verify that an HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol before the candidate will appear on match runs for HIV positive organs.

Vessel Storage

The initial proposal included adding "HIV positive" extra vessels to the list of vessels that cannot be stored. The work group is proposing a slight modification to the language in Policy 16.7: *Vessel Recovery, Transplant, and Storage* by specifying "HIV positive by antibody, antigen, or nucleic acid test (NAT)."

Labels

The work group reviewed the remainder of Policy 16: *Organ and Vessel Packaging, Labeling, Shipping, and Storage*. There was concern that adding infectious disease information to the external label could create problems with commercially shipped organs. There was some discussion about making changes only to the internal organ labels; however, the group noted that no infectious disease results are currently included on the labels for HCV, HBV, and other diseases. The work group agreed that no policy changes or label changes were needed at this time but they will continue to evaluate this issue as they prepare for implementation of the HOPE Act. The work group noted that future changes can be developed as needed and that future implementation of the organ tracking system might help address this issue.

Terminology Changes

During the review of the policies the work group noted the use of "serology results." Since infectious disease testing can be completed using a variety of methods besides serology testing the work group agreed that changing the terminology to "infectious disease testing results" will provide more consistency. Additionally, when specific tests are required, these are addressed in the policies. The work group proposes changing "serology results" to "infectious disease testing results" within Policies 13.6.B: *Requirements for Match Run Eligibility for Potential KPD Donors*, 15.4.A: *Transplant Program Requirements*, 16.7.C: *Blood Type Verifications Prior to Transplant*

of Deceased Donor Vessels, and 16.7.E: Blood Type Verification Prior to Transplant of Living Donor Vessels.

Another issue identified by the work group during its policy review was the use of the term “authorization” in Policy 2.7.A: *Exceptions to HIV Screening Requirements*. The proper term is “informed consent” so the work group is proposing an update to this policy.

Re-Execution of the Match Run

The work group discussed the need to require the re-execution of a match run if infectious disease testing results are received that indicate the donor is HIV positive. Work group members noted that there is a current joint effort by the DTAC, Operations and Safety Committee, and OPO Committee to require this for other diseases such as HCV, HBV, HTVL, and CMV. The work group agreed that HIV should be included in that effort and will be part of a separate proposal.

Supporting Evidence and/or Modeling:

The OPTN does not currently collect the HIV status of candidates on the waiting list. For this reason, the exact number of potential candidates that could benefit from this policy change is unknown. However, over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year.³

Expected Impact on Living Donors or Living Donation:

It is anticipated that living donors will be included in the research protocols being developed by the NIH. However, before removing HIV from the exclusion criteria listed in Table 14-2: *Requirements for Living Kidney Donor Medical Evaluations* the group will seek input from the Living Donor Committee and the transplant community.

Expected Impact on Specific Patient Populations:

This proposal will lead to the increased availability of organs for candidates with HIV. Boyarsky et al maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year.⁴

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal supports the OPTN’s Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

³ Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. *American Journal of Transplantation*, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

Plan for Evaluating the Proposal:

This proposal is another step in the process to amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS). According to the HOPE Act, the Secretary of HHS will work in conjunction with the OPTN to review the results of scientific research by November 21, 2017.

Six months after the first HIV positive donor transplant is performed as part of the research study the committee will review the following information:

- The number of HIV positive donor transplants performed by organ type
- The number of transplant programs approved, and the number performing these transplants
- The number of OPOs with at least one HIV positive deceased donor recovered
- The number of candidates indicated as willing to accept an organ from an HIV positive donor
- The number of unintended HIV donor transmissions.

These data will be updated twice a year for at least three years after the first transplant is performed. Once enough HIV positive donor transplants have been performed, Kaplan-Meier patient and graft survival rates at 6 months and one year post-transplant will be included along with the other data points.

Additional evaluation planning will be required as more information is known about the research protocols.

Additional Data Collection:

The additional data being collected as part of the research study are still being drafted by the NIH. There are indications from HRSA/NIH that the OPTN will be responsible for collecting the additional data as outlined in the research protocols. These include such data as HIV status, CD4+ T cell counts, viral load, HIV-1 RNA, donor allograft biopsy, co-infections (HCV, HBV), and antiretroviral therapy resistance. Please note that the data reporting requirements have not been finalized and therefore no policy changes dealing with data submission are being proposed at this time. The methods used to collect these data, if it becomes a charge of the OPTN, are being evaluated and information will be provided as it becomes available.

Expected Implementation Plan:

If public comment on the HOPE Act proposals is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect concurrent with the implementation of the HOPE Act in November, 2015.

While the NIH continues to work on drafting the research protocols, the OPTN has been evaluating the programming needs to facilitate the recovery and transplantation of HIV positive organs. Initial estimates indicate an "Enterprise" size project as staff identifies potential programming changes for both deceased and living donation. This includes updates to the membership database to identify those transplant centers with institutional review board approval to participate in the research study and additional changes to donor screening and candidate screening. At this time, there is no plan to facilitate the matching of HIV positive donors and recipients based on additional clinical information for HIV. Standard match runs for kidneys and livers will be used with screening of candidates based on HIV positive status and willingness to accept an HIV positive organ. The work group will be working with UNOS staff to determine and finalize the programming requirements prior to implementation.

Communication and Education Plan:

The proposal would apply to hospitals performing HIV positive transplants and OPOs that would recover HIV positive organs. Communication and education efforts would thus focus on the specific details of the policy modifications and support members may need to revise their processes.

Information about the policy modifications would be included in an effort to provide communication and instruction to members, with emphasis on impacted practices at transplant programs and OPOs.

In addition, notification of the policy modifications would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Member e-newsletter/member communications
- Communication to appropriate list serves

Compliance Monitoring:

Staff will continue reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements, and will continue investigating potential policy violations. Based upon the proposed language, the following would be added to the current routine monitoring of members:

Policy 16.7.B - At transplant hospitals, site surveyors will review the transplant hospital's internal policies, procedures and/or protocols and interview key clinical personnel, as necessary, to verify that they address that HIV+ vessels are not stored for later use.

Policy or Bylaw Proposal:

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

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 an increased risk for disease transmission based on current U.S. Public Health Services (PHS) Guideline.

In this case the receiving transplant hospital must:

1. Obtain and document informed ~~authorization~~ consent from the potential transplant recipient or the recipient's authorized agent before transplantation.

5.3.C 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 Contractor.

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

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with non-A₁ blood type
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. 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
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft
8. If a candidate is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

5.4.F 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. OPOs may not allocate HIV positive organs, as described in Policy 15.5: *Policy 15.5: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*, to candidates not appearing on the match run.

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. That the transplant hospital verified the medical suitability between the deceased donor organ and recipient prior to transplant 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

The transplant hospital must maintain all related documentation.

14.4.E Living Donor Exclusion Criteria

Table 14-9: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	<p>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.</p> <p>Living donor recovery hospitals must exclude all donors who meet <i>any</i> of the following exclusion criteria:</p> <ul style="list-style-type: none"> • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, <u>unless the requirements for a variance are met, according to <i>Policy 15.5 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors</i></u> • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
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15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when *any* of the following occurs:

- The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, including HIV. ~~with the exception of HIV, which must be handled according to *Policy 2.7: HIV Screening of Potential Deceased Donors* or exclusionary criteria in *Table 14-2 (Requirements for Living Donor Kidney Medical Evaluations)*.~~
- The deceased donor meets the guidelines for an increased-risk of transmissible disease as specified in the *U.S. Public Health Services (PHS) Guideline*.
- When a hemodiluted specimen is used for deceased donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are only required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
3. That there is no comprehensive way to screen potential deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.4.A Transplant Program Requirements

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition, including infections and malignancies, and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *both* of the following:

1. Notify the institution that recovered the organ (OPO or living donor recovery hospital), without waiting for all medical documentation that may eventually become available. The transplant program must notify the living donor hospital or host OPO by phone and provide documentation as soon as possible but no later than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal.

Any transplant program treating recipients that received organs from a donor who is the subject of a potential disease transmission report is responsible for *all* of the following:

1. Responding to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding all recipients in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
2. Submitting copies of any relevant test results including cultures, ~~serologies~~ infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
3. Notifying recipients involved in cases of confirmed disease transmissions and documenting this notification in the recipient medical record according to *15.3.A: Requirements for Identified Increased Risk of Transmissible Disease*.
4. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial date the potential transmission was reported.

OPTN patient safety staff may request additional information related to the recipient beyond 45 days, in an effort to determine the probability of donor-derived disease transmission, depending on the potentially transmitted disease or malignancy.

15.5 Open Variance for the Recovery and Transplantation of Organs from HIV-Positive Donors

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

15.5.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate organs only after determining the potential deceased donor to be HIV positive for transplant into an HIV positive candidate who is willing to accept an HIV positive organ as part of the research protocol.

15.5.B Requirements for Allocating HIV Positive Living Donor Organs

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

15.5.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs

In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant organs known to be infected with HIV only if *all* of the following conditions are true:

1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from individuals known to be infected with HIV.
2. The transplant hospital obtains informed consent from the potential transplant recipient to participate in the institutional review board protocol that meets requirements in the OPTN Final Rule.
3. The transplant hospital meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*.

In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or livers, the transplant hospital 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 Contractor that the candidate is willing to accept an HIV positive organ as part of a research protocol.

16.7.B Vessel Recovery, Transplant, and Storage

Transplant hospitals may not store for later use any extra vessels from donors who are HIV positive by antibody, antigen, or nucleic acid test (NAT), hepatitis C antibody positive (HCV), hepatitis C (HCV) NAT positive, or hepatitis B surface antigen positive (HBsAg), or hepatitis B (HBV) NAT positive. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

16.7.C Blood Type Verification Prior to Transplant of Deceased Donor Vessels

The transplant hospital must verify the blood type, all ~~serology~~ infectious disease testing results, container contents, date of expiration, and the Donor ID of the vessels with the blood type and all ~~serology~~ infectious disease testing results of the recipient prior to transplant. These verifications must be documented and maintained in the recipient medical record.

16.7.E Blood Type Verification Prior to Transplant of Living Donor Vessels

Prior to transplant, the recovery hospital must verify *all* of the following:

1. The living donor's blood type
2. The living donor's blood subtype, if used for allocation
3. All ~~serology~~ infectious disease testing results
4. Container contents
5. Date of expiration
6. Donor ID

The transplant hospital must also verify the blood type and subtype of the intended recipient, if used for allocation, and all ~~serology~~ infectious disease testing results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.