OPTN

Notice of OPTN Policy Changes

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

Sponsoring Committee: Ad Hoc Disease Transmission Advisory

Policy Affected:

Policy 1.2: Definitions
Policy 2.7: HIV Screening of Potential Deceased Donors
Policy 2.7.A: Exceptions to HIV Screening Requirement
Policy 5.3.B: Infectious Disease Screening Criteria
Policy 5.3.D: Liver Acceptance Criteria
Policy 5.3.H: Kidney Offer Filters
Policy 5.4.E: Allocation to Candidates Not on the Match Run
Policy 5.5.C: OPO Requirements for Positive HIV Results
Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt
Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt
Policy 14.3: Informed Consent Requirements
Policy 14.4.E: Living Donor Exclusion Criteria
Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements
Policy 15.3.B: Donors with Risk Identified Pre-Transplant
Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors
Policy 15.7.A: Requirements for Allocating HIV Positive Deceased Donor Organs
Policy 15.7.B: Requirements for Allocating HIV Positive Living Donor Organs
Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs
Policy 16.6.A: Extra Vessels Use and Sharing

Public Comment:	**March 21 – April 22, 2025**
Board Approved:	**June 10, 2025**
Effective Date:	**June 26, 2025**

Purpose of Policy Change

The purpose of this policy change is to align with federal regulatory changes that expand access for liver and kidney candidates living with human immunodeficiency virus (HIV), while still maintaining patient safety for all transplant candidates and potential living donors. OPTN policy and the OPTN Computer System are therefore modified to align with the HIV Organ Policy Equity (HOPE) Act changes detailed in the 2024 amended OPTN Final Rule and National Institutes of Health (NIH) Final Notice, which remove the requirement for NIH research criteria and participation in the OPTN HOPE Act variance for the transplantation of livers, kidneys, and liver-kidneys from donors with HIV to candidates living with HIV.[1,2,3] The HOPE Act has been demonstrated to be a successful effort to safely improve access to transplant for candidates living with HIV. The proposed changes access expands so that more individuals living with HIV are able to obtain an organ transplant, while adding candidate status verification and living donor consent elements to ensure patient safety is maintained.

Proposal History

The 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 NIH research criteria.[4] This ended a prohibition in the United States of the transplant of organs from donors with HIV. Since its initial implementation, the OPTN HOPE Act variance has been extended to apply to all organs from just livers and kidneys. 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.[5]

This current proposal removes the OPTN HOPE Act variance and NIH research criteria requirements for liver, kidney, and liver-kidney transplants, in alignment with the 2024 federal regulatory changes. Implementation on June 26, 2025 reflects direction from the Health Resources and Services Administration (HRSA) to implement these changes on an accelerated timeline.

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[1] At the end of 2024, Health and Human Services Department (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. 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.

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

[3] 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).

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

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

Summary of Changes

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 (relevant policies are noted in parentheses):
    - 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 (Policies 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 (Policy 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 (14.3);
- 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;[6,7] and
- Reporting of data safety monitoring reports by transplant programs participating in the OPTN HOPE Act variance is clarified to be upon request by the OPTN (15.7.D).

Implementation

Liver & Kidney Programs

- Security admins will be able to grant permission to users to verify candidate is living with HIV and willing to accept an HIV organ
    - Transplant physician must verify in candidate record, prior to two person reporting requirement in OPTN Waiting List
- If candidate's status has previously been verified in OPTN Waiting List:
    - Document re-verification in medical record by transplant physician
    - No modification to OPTN Waiting List needed unless candidate consent changes

[6] OPTN Organ Procurement Organization Committee Leadership Call, January 2025.
[7] OPTN Ad Hoc Disease Transmission Advisory Committee Leadership Call, January 2025.

- If candidate status previously verified at program without current IRB approval:
    - For patient safety reasons, OPTN Waiting List status will revert to 'no'
    - OPTN Contractor outreach to confirm patient and program awareness (small population)
- Transplant physician obtains informed consent when candidate receives an offer from a donor with a positive HIV test
    - Informed consent form pre-op acceptable for documentation
- Transplant surgeon and licensed healthcare professional verify candidate status and willingness to receive an organ from a donor with HIV in candidate medical record prior to transplant
- Living liver or kidney programs must consent living donors with HIV about lack of data on long-term impact of donating while living with HIV

All transplant programs

- Double verification of candidate status and willingness to accept HIV organ will continue in OPTN Waiting List
- OPTN Computer System will continue to default to 'no' for willingness to accept HIV positive organ offers for new and currently listed patients
- No specific restrictions on pediatric candidates (as long as all other standards are met for non-liver and non-kidney organs)

Non-liver and non-kidney programs

- If program intends to list and treat only a single candidate, OPTN will continue to accept an IRB approval for a single candidate as long as all other standards are met

OPOs

- Awareness that non-liver and non-kidney organs require participation in HOPE Act variance and that the exception to HIV screening is removed from policy

OPTN

- Implementation for the OPTN includes updates to the OPTN Computer System (coding and testing), as well as providing communications and educational materials to the community.
    - These include an updated HOPE Act Toolkit on the OPTN website, a webinar (recording on the OPTN website), an educational module and community outreach.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

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)

o 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 <u>from a donor with HIV</u> for transplantation into a~~n HIV positive~~ recipient <u>living with HIV</u> 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 <u>with HIV</u>* 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. <u>Allocation of organs from deceased donors with HIV must follow the requirements</u>

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

The transplant hospital must verify all of the following information:	Using at least one of the following:	By *both* of the following individuals:
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 verification of donor and recipient blood types	Two licensed health care professionals
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
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
<u>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</u>	• <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of HIV status of donor and candidate</u>	1. <u>Transplant surgeon</u> 2. <u>Licensed health care professional</u>

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
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.

The recovery hospital must:	These elements of informed consent:
	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 • 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*.

The recovery hospital must:	These elements of informed consent:
	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 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

The recovery hospital must:	These elements of informed consent:
	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

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
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
	  ○ the living donor is donating a non-kidney or non-liver organ, and
	  ○ ~~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
	  ○ requires treatment other than surveillance or
	  ○ 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
	  ○ evidence of end organ damage or
	  ○ 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~~ living 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,~~ tThe 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.[8]
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.*

[8] 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.

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.