OPTN

*Notice of OPTN Policy Changes*

# Align OPTN Policy with U.S. Public Health Service Guideline, 2020

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| **Sponsoring Committee:** | **Ad Hoc Disease Transmission Advisory** |
| **Policies Affected:** | ***1.2: Definitions*** |
| | ***2.2: OPO Responsibilities*** |
| | ***2.4: Deceased Donor Medical and Behavioral History*** |
| | ***2.5: Hemodilution Assessment*** |
| | ***2.7.A: Exceptions to HIV Screening Requirement*** |
| | ***2.9: Required Deceased Donor Infectious Disease Testing*** |
| | ***13.11: Receiving and Accepting KPD Match Offers*** |
| | ***14.1.A: Living Donor Psychosocial Evaluation Requirements*** |
| | ***14.3: Informed Consent Requirements*** |
| | ***14.4.A: Living Donor Medical Evaluation Requirements*** |
| | ***14.8.B: Living Donor Specimen and Storage*** |
| | ***14.9.B: Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors*** |
| | ***15.2: Potential Candidate Screening Requirements*** |
| | ***15.3.B: Donors with Risk Identified Pre-Transplant*** |
| | ***15.3.C: Recipients of Organs from Donors with Increased Risk of Disease Transmission*** |
| | ***16.3.D: Internal Labeling of Extra Vessels*** |
| **Public Comment:** | **August 4, 2020 – October 1, 2020** |
| **Board Approved:** | **December 7, 2020** |
| **Effective Date:** | **June 1, 2021 (Policy 14.8.B; Policy 14.3)** |
| **Effective Date (All other changes):** | **Pending implementation and notice to OPTN Members** |

## Purpose of Policy Changes

This policy change aligns OPTN policies with revised U.S 2020 U.S. Public Health Service (PHS) Guideline for assessing solid organ donors and monitoring transplant recipients for HIV, HBV, and HCV infection, as required by the Final Rule.[1] [2]

## Proposal History

The revisions published by the PHS are in response to concerns by the OPTN and the greater transplant community that more donors were being classified as increased risk than necessary to achieve patient safety, and it was leading to unnecessary discard or turndowns of these donated organs. Organ transplant candidates who are on the waiting list are at high risk for death, and those who decline organs designated as increased risk have higher rates of death and graft failure than patients who accept increased risk organs. The 2020 revisions to criteria are overall less restrictive than the current ones, with the additional safeguards of more testing on donors and recipients to identify potential disease transmission.

The community is overwhelmingly supportive of the proposed less restrictive risk criteria in an effort to increase the number of safe transplants overall. While potential changes to the proposal are limited due to Final Rule requirements to be consistent with CDC recommendations, one substantive change to the proposal resulted from public comment. Policy language was added to existing living donor informed consent requirements to ensure that living donors are appropriately consented for the new ten year living donor specimen storage requirement (no longer proposed).

## Summary of Changes

Major categories of policy modifications update existing OPTN policy to reflect recommendations outlined in the updated PHS publication include:

- Risk assessment of living and deceased donors
    - Change the definition of *US PHS Guideline* to refer to the 2020 version which results in:
        - Shorter risk criteria inclusionary timeframe from twelve months to one month
        - Removal of four risk criteria, including hemodialysis and hemodilution
    - Remove specific label of “increased risk donor” (IRD)
- Living and deceased solid organ donor testing
    - Add required HBV NAT and HIV NAT testing for all living and deceased organ donors:
    - Require deceased donor testing specimens to be collected within 96 hours of organ procurement
- Transplant candidate informed consent
    - Remove requirement to obtain specific “informed consent”
    - Add requirement that transplant hospitals inform intended recipients when the donor has any risk criteria
- Recipient testing and reporting
    - Add specific timing and testing type requirements for candidate pre-transplant testing of HIV, HBV, and HCV (during hospital admission for transplant but before transplant)

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[1] 42 C.F.R. §1 21.4(a)(2).

[2] JM Jones, I Kracalik, ME Levi, et al, “Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020,” *Morbidity and Mortality Weekly Report*, 69, (No. RR-4), June 26, 2020, 1-16, http://dx.doi.org/10.15585/mmwr.rr6904a1.

    - Add requirement to assess and report candidate HBV vaccination status including reasons if vaccination not completed
    - Add universal post-transplant testing for all recipients, regardless of donor risk criteria
        - HIV, HBV, and HCV NAT testing at four to eight weeks post-transplant
        - HBV NAT testing at eleven to thirteen months post-transplant for liver recipients
- Collection and storage of donor and recipient specimens
    - Add requirement for living donor recovery hospitals to store specimens to ten years
    - Add required disclosure to existing Living Donor informed consent policy for specimen storage
    - Add requirement to obtain storage specimen within 24 hours of organ recovery for both deceased and living donors

## Implementation

Transplant hospitals must arrange for storage for living donor specimens (living donor hospitals) and modify living donor informed consent and arrange for additional pre and post-transplant testing for HIV, HBV, and HCV. Hospitals must also assess candidates for the need for HBV vaccination and report HBV vaccination status including reason if HBV vaccination cannot be completed or initiated prior to transplant.

OPOs must modify donor screening questions and documentation for identifying donors that have any risk criteria, obtain NAT testing for HIV, HBV, and HCV within 96 hours of procurement, and upgrade their TransNet℠ application upon release and use revised extra vessels labels.

OPTN programming changes include:

- Changes in in UNet℠, DonorNet®, Mobile℠ , and TransNet℠
- Transplant Recipient Registration (TRR) forms in Transplant Information Electronic Data Interchange (TIEDI®) will have new data collection for recipient HBV vaccination status
- Extra vessel label changes from “PHS Increased Risk” to “HIV/HCV/HBV Risk Criteria”
- Changes to transplant recipient follow-up (TRF) viral detection section to report testing

Educational efforts include information members and patients in for the form of educational webinars and other media products, and an updated Frequently Asked Questions (FAQ) page.

## Affected Policy Language

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

### 1.2 Definitions:

**Hepatitis B Virus (HBV)**
Hepatitis B is a vaccine-preventable liver infection caused by the hepatitis B virus (HBV).

**Hepatitis C Virus (HCV)**
Hepatitis C is a liver infection caused by the hepatitis C virus (HCV).

**Human Immunodeficiency Virus (HIV)**

Human Immunodeficiency Virus (HIV) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to Acquired Immunodeficiency Syndrome (AIDS).

**United States (U.S.) Public Health Service (PHS) Guideline**
~~The *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation* (2013).~~

The Guideline issued by the U.S. Public Health Service in 2020 that provides recommendations for organ transplantation related to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) transmission.

## 2.2 OPO Responsibilities

15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

## 2.4 Deceased Donor Medical and Behavioral History

The medical and behavioral history for each potential deceased donor must include all of the following:

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.

2. Whether the potential deceased donor has any risk factors associated with ~~an increased risk for~~ disease transmission, including blood-borne pathogens. If the deceased donor ~~meets the~~ has any risk criteria for ~~increased risk for~~ acute HIV, ~~Hepatitis B~~ HBV, ~~and~~ or ~~Hepatitis C transmission~~ HCV infection ~~as set forth in~~ according to the ~~current~~ *U.S. Public Health Services (PHS) Guideline* ~~or the host OPO cannot obtain the information necessary to make this determination,~~ the host OPO must ~~identify the donor as having increased risk for transmission of HIV, Hepatitis B, and Hepatitis C and~~ communicate this information to all transplant programs receiving organs from the deceased donor.

## 2.5 Hemodilution Assessment

OPOs must use qualified (non-hemodiluted) blood samples for deceased donor ~~serological~~ screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample may be used for deceased donor screening tests.

~~If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased donor as presenting an increased risk for disease transmission as specified in the U.S. Public Health Services (PHS) Guideline.~~

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for ~~serological~~ screening tests for hemodilution using a ~~U.S. Food and Drug Administration~~

~~(FDA) approved~~ hemodilution calculation. The host OPO must document in the deceased donor medical record a complete history of all blood products and intravenous fluid transfusions the deceased donor received since admission to the donor hospital.

Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a hemodiluted specimen is used in deceased donor screening tests:

1. Any screening results from the hemodiluted specimens.
2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

### 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~~ any risk criteria for ~~disease transmission~~ acute HIV, HBV or HCV infection ~~based on current~~ according to the *U.S. Public Health Service~~s~~ (PHS) Guideline*.

In this case the receiving transplant hospital must:

- ~~Obtain and document informed consent from~~ 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*

## 2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA) ~~CLIA-~~certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
   a. HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
   b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   c. Hepatitis B surface antigen (HBsAg) donor screening test
   d. Hepatitis B core antibody (total anti-HBc) donor screening test
   e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
   f. Hepatitis C antibody donor screening test (anti-HCV)

g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening or diagnostic test
i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening or diagnostic test
j. Syphilis donor screening or diagnostic test
k. Toxoplasma Immunoglobulin G (IgG) antibody test

3. ~~If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*. HIV RNA by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination is *also* required unless *either* of the following is true:~~
   - ~~The donor has already been tested for HIV using the HIV Ag/Ab combination test according to section 2.a above.~~
   - ~~The donor's only increased risk factor is having received hemodialysis within the past 12 months.~~

   Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.

## 13.11 Receiving and Accepting KPD Match Offers

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

**Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer**

| The following members: | Must: | Within: |
|---|---|---|
| Each transplant hospital receiving a match offer | Report to the OPTN Contractor a preliminary response | 2 business days of receiving the match offer. |
| The matched candidate's transplant hospital and the matched donor's transplant hospital | Agree in writing upon all of the following:<br>• Contents required in the crossmatch kit<br>• Instructions for the donor<br>• Address at which to send the completed blood samples | 4 business days of receiving the match offer. |
| The matched donor's transplant hospital | Report to the OPTN Contractor the agreed upon date of the crossmatch | 4 business days of receiving the match offer. |
| The matched donor's transplant hospital | Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:<br>• Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital<br>• Whether the matched donor ~~is increased risk~~ has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service~~s~~ (PHS) Guideline*<br>• Additional records requested by the matched candidate's transplant hospital | 4 business days of receiving the match offer. |
| The matched candidate's transplant hospital | Report to the OPTN Contractor the results of the crossmatch | 15 business days of receiving the match offer. |
| The matched candidate's transplant hospital | Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor | 15 business days of the match offer. |

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

### 14.1.A Living Donor Psychosocial Evaluation Requirements

Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung, and intestine donors.

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, masters prepared social worker, or licensed clinical social worker prior to organ recovery. Documentation of the psychosocial evaluation must be maintained in the living donor medical record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome.
2. An ~~evaluation for the presence of behaviors that may increase~~ assessment of risk criteria for ~~disease transmission~~ acute HIV, HBV, and HCV infection ~~as defined by~~ according to the *U.S. Public Health Service (PHS) Guideline.*
3. A review of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder.
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision.
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation.
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended.
8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support.
9. The determination that the living donor understands the potential financial implications of living donation.

## 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 apply to living kidney, liver, pancreas, intestine, and lung donors and must include *all* of the components in *Tables 14-1* through *14-4*. 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:<br>1. Is willing to donate<br>2. Is free from inducement and coercion<br>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.<br>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.*<br>3. Instruction about all phases of the living donation process, which includes:<br>• Consent<br>• Medical and psychosocial evaluations<br>• Pre- and post-operative care<br>Required post-operative follow-up according to *Policy 18.4: Living Donor Data Submission Requirements.*<br><br>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.<br>2. The recovery hospital must provide an ILDA.<br>3. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation.<br>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.<br>5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment.<br>6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient.<br>7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:<br>• Exceed local or national averages<br>• Do not necessarily prohibit transplantation<br>• Are not disclosed to the living donor<br>8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: |

| The recovery hospital must: | These elements of informed consent : |
|---|---|
| | • The reasons for a transplant candidate's increased likelihood of adverse outcomes<br>• Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law<br>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.<br>10. The recovery hospital is required to:<br>a. Report living donor follow-up information, at the time intervals specified in *Policy 18.5: Living Donor Data Submission Requirements*<br>b. Have the donor commit to post donation follow-up testing coordinated by the recovery hospital.<br>c. <u>Obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease.</u><br>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:<br>a. May need to be reported to local, state or federal public health authorities<br>b. Will be disclosed to their recipient's transplant hospital<br>c. Will be reported through the OPTN Improving Patient Safety Portal<br>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*.<br>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<br>14. The following are inherent risks associated with evaluation for living donation:<br>a. Allergic reactions to contrast<br>b. Discovery of reportable infections<br>c. Discovery of serious medical conditions<br>d. Discovery of adverse genetic findings unknown to the living donor<br>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<br>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:<br>a. Potential medical or surgical risks:<br>i. Death<br>ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical |

| The recovery hospital must: | These elements of informed consent : |
|---|---|
| | procedure<br>iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction<br>iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions<br>b. Potential psychosocial risks:<br>i. Problems with body image<br>ii. Post-surgery depression or anxiety<br>iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies<br>iv. Changes to the living donor's lifestyle from donation<br>c. Potential financial impacts:<br>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<br>ii. Need for life-long follow up at the living donor's expense<br>iii. Loss of employment or income<br>iv. Negative impact on the ability to obtain future employment<br>v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance<br>vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance |

### 14.4.A Living Donor Medical Evaluation Requirements

Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or intestine donors.

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-5* through *14-8* below.

**Table 14-5: Requirements for Living Donor Medical Evaluations**

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|---|---|
| **General donor history** | 1. A personal history of significant medical conditions which include but are not limited to:<br>a. Hypertension<br>b. Diabetes<br>c. Lung disease<br>d. Heart disease<br>e. Gastrointestinal disease<br>f. Autoimmune disease<br>g. Neurologic disease<br>h. Genitourinary disease<br>i. Hematologic disorders<br>j. Bleeding or clotting disorders<br>k. History of cancer including melanoma<br>2. History of infections<br>3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication<br>4. Allergies<br>5. An evaluation for coronary artery disease |
| **General family history** | • Coronary artery disease<br>• Cancer |
| **Social history** | • Occupation<br>• Employment status<br>• Health insurance status<br>• Living arrangements<br>• Social support<br>• Smoking, alcohol and drug use and abuse<br>• Psychiatric illness, depression, suicide attempts<br>• ~~Increased risk behavior~~ Risk criteria for acute HIV, HBV, and HCV infection ~~as defined by~~ according to the *U.S. Public Health Services (PHS) Guideline* |
| **Physical Exam** | • Height<br>• Weight<br>• BMI<br>• Vital signs<br>• Examination of all major organ systems |
| **General laboratory and imaging tests** | • Complete blood count (CBC) with platelet count<br>• Blood type and subtype as specified in 14.5: Living Donor Blood Type Determination and Reporting and its subsections<br>• Prothrombin Time (PT) or International Normalized Ratio (INR)<br>• Partial Thromboplastin Time (PTT) |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|---|---|
| | • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)<br>• HCG quantitative pregnancy test for premenopausal women without surgical sterilization<br>• Chest X-Ray<br>• Electrocardiogram (ECG) |
| **Transmissible disease screening** | Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following:<br><br>1. CMV (Cytomegalovirus) antibody<br>2. EBV (Epstein Barr Virus) antibody<br>3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery<br>4. <u>HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</u><br>5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery<br>6. Hepatitis B core antibody (<u>total</u> anti-HBc) testing as close as possible, but within 28 days prior to organ recovery<br>7. <u>HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</u><br>8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery<br>9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery<br>10. Syphilis testing<br><br>~~If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the *U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline.*~~<br><br>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*:<br><br>• Intradermal PPD<br>• Interferon Gamma Release Assay (IGRA) |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|---|---|
| **Endemic transmissible diseases** | Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation. |
| **Cancer screening** | Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:<br>• Cervical cancer<br>• Breast cancer<br>• Prostate cancer<br>• Colon cancer<br>• Lung cancer |

### 14.8.B Living Donor Specimen Collection and Storage

The recovery hospital must obtain specimens appropriate for serological and NAT testing within 24 hours prior to organ recovery. The recovery hospital is responsible for arranging storage of these specimens for at least 10 years after the date of transplant and ensuring these samples are available for retrospective testing. The recovery hospital must document the type of sample in the living donor medical record.

### 14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors

Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according to *all* of the following requirements:

1. Perform an ~~evaluation for the presence of behaviors that may increase risk for disease transmission~~ assessment for risk criteria for acute HIV, HBV, and HCV infection ~~as defined by~~ according to the *U.S. Public Health Service (PHS) Guideline*
2. Screen the domino donor or non-domino therapeutic donor for all of the following according to *Policy 14.4: Medical Evaluation Requirements for Living Donors*, *Table 14-5: Requirements for Living Donor Medical Evaluations*:
   a. Transmissible diseases screening
   b. Endemic transmissible diseases
   c. Cancer screening
3. Develop and comply with written protocols for the domino donor and non-domino therapeutic donor exclusion criteria considering incorporating as appropriate the elements of *Table 14-8: Living Donor Exclusion Criteria*
4. Register and verify the blood type of the domino donor or non-domino therapeutic donor according to *Policy 14.5: Registration and Blood Type Verification of Living Donors before Donation*

Documentation of the psychosocial and medical evaluation must be maintained in the donor medical record.

## 15.2 ~~Potential~~ Candidate ~~Screening~~ Pre-Transplant Infectious Disease Reporting and Testing Requirements

To be eligible for an organ transplant, ~~potential~~ transplant candidates must be tested for:

1. ~~human immunodeficiency virus (~~HIV~~)~~ using a CDC recommended laboratory HIV testing algorithm
2. ~~hepatitis B,~~ Hepatitis B surface antigen (HBsAg)
3. Hepatitis B core antibody (total anti-HBc)
4. Hepatitis B surface antibody (HBsAb)
5. ~~and hepatitis C,~~ 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.

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 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.

~~Potential c~~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 judgment, the reason for not initiating or completing HBV vaccination must be documented in the candidate's medical record and reported to the OPTN.[3]

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

[3] The language in this paragraph is substantially similar to the original proposal on HBV vaccination status reporting that was sent to public comment in August of 2020. The Ad Hoc Disease Transmission Advisory Committee decided to relax the data collection requirement in the proposal at its meeting on October 26, 2020. The Committee revisited the issue at its December 1, 2020 meeting and voted on the language presented here. Due to the timing of the second meeting, a previous version of this Briefing Paper had the October 26 language. This Briefing Paper accurately reflects the Committee's approved proposal to the Board of Directors.

### 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:<br>a. Hepatitis B surface antigen (HBsAg)<br>b. Hepatitis B nucleic acid test (NAT)<br>c. Hepatitis C NAT<br>~~• The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified in the *U.S. Public Health Services (PHS) Guideline*~~<br>~~• A hemodiluted specimen is used for the donor HIV, hepatitis B, or hepatitis C testing, according to *Policy 2.5: Hemodilution Assessment*~~<br>• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors* | 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<br>2. Document this consent in the intended recipient's medical record<br>3. Follow the recipient for the development of potential donor-derived disease after transplant |
| • <u>The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*</u> | <u>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</u><br><u>2. Document that this information was provided in the intended recipient's medical record</u> |

~~Exceptions to the informed consent requirement may be made for extra vessels when,~~ <u>If</u> in the medical judgment of the transplanting physician, ~~the~~ extra vessels are required for use in an emergency transplant procedure for an organ other than the organ with which they were recovered~~. In this case~~, <u>then</u> the transplant hospital must do *both* of the following post-transplant:

1. Inform the recipient of the use of the extra vessels and <u>if the donor had any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*</u> ~~the increased risk status~~

2. Provide follow up to the recipient according to *Policy ~~15.3.B: Donors with Risk Identified Pre-Transplant~~ 15.3.C: Required Post-Transplant Infectious Disease Testing*

### 15.3.C ~~Recipients of Organs from Donors with Increased Risk of Disease Transmission~~ Required Post-Transplant Infectious Disease Testing

1. Transplant programs must test all recipients post-transplant for: ~~develop and comply with a written protocol for post-transplant testing for HIV, hepatitis B, or hepatitis C, for recipients who receive an organ from a donor who meets any of the criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified in the *U.S. Public Health Services (PHS) Guideline*.~~

   A. HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
   B. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
   C. HCV ribonucleic acid (RNA) by nucleic acid test (NAT)

2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant.
3. If the candidate is known to be infected 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.

4. The transplant program must offer recipients ~~of these donor organs *both* of the following:~~

~~1. Additional post-transplant testing for HIV, hepatitis B , and hepatitis C according to the transplant program's protocol~~
~~2. T~~treatment of or prophylaxis for ~~the transmissible disease~~ HIV, HBV, or HCV, when medically appropriate.

5. Transplant programs must conduct HBV NAT testing on liver recipients at least 335 days but no later than 395 days post-transplant.

### 16.3.D Internal Labeling of Extra Vessels

The rigid container holding the extra vessels and the outermost layer of the triple sterile barrier must each have a completed OPTN extra vessels label. The OPTN Contractor distributes standardized labels that must be used for this purpose. The internal label on the outermost layer of the triple sterile barrier must be completed using the OPTN organ tracking system. The labels must include *all* of the following information according to *Table 16-1* below.

**Table 16-1: Required Information on Internal Labels for Vessels**

| This information must be included: | On the rigid container: | On the outermost layer of the triple sterile barrier: |
|---|---|---|
| 1. Donor ID | ● | ● |
| 2. Donor blood type | ● | ● |

| This information must be included: | On the rigid container: | On the outermost layer of the triple sterile barrier: |
|---|---|---|
| 3. Donor blood subtype, if used for allocation | ● | ● |
| 4. Recovery date | ● | ● |
| 5. Description of the container contents | ● | ● |
| 6. That the extra vessels are for use in organ transplantation only | ● | ● |
| 7. All infectious disease testing results for *all* of the following:<br>a. anti-HIV I/II<br>b. HIV Ag/Ab combo<br>c. HIV NAT<br>d. <u>total</u> anti-HBc<br>e. HBsAg<br>f. HBV NAT<br>g. anti-HCV<br>h. HCV NAT | | ● |
| 8. Whether the extra vessels are from a donor with a positive result (NAT included) for *any* of the following:<br>• HIV, HBV, or HCV<br>• <u>total</u> anti-HBc | ● | |
| 9. Whether the extra vessels are from a donor that ~~meets the~~ <u>has any risk</u> criteria ~~for increased risk of transmitting~~ <u>for acute</u> HIV, ~~hepatitis B~~ <u>HBV</u>, or ~~hepatitis C~~ <u>HCV infection</u>, ~~as specified in~~ <u>according to</u> the *U.S. Public Health Service (PHS) Guideline* | ● | ● |

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