Policy Notice

OPTN
Organ Procurement & Transplantation Network

Shortened Testing Window for HIV and West Nile Virus

Sponsoring Committee: OPTN Ad Hoc Disease Transmission Advisory Committee

Board Approved: June 18, 2026

Effective Date: August 17, 2026

Purpose of Policy Changes

The purpose of these policy changes is to improve patient safety by reducing the risk of donor-derived transmission of Human Immunodeficiency Virus (HIV) and West Nile Virus (WNV) through solid organ transplantation.

Recent donor-derived transmission events demonstrated that the existing testing windows for HIV and WNV may not detect infections acquired shortly before organ recovery. Although testing was completed in accordance with OPTN policy, infections occurring after donor testing but before organ recovery resulted in transmission to transplant recipients.

To reduce this risk, the OPTN Board of Directors approved emergency policy changes requiring HIV and WNV testing to be performed as close as possible to organ recovery, but within 7 days prior to organ recovery for living donors.

These changes strengthen donor infectious disease screening and better align testing with the period of greatest clinical relevance immediately preceding organ recovery.

Policies Affected

Policy Number	*Policy Name*
14.4	Medical Evaluation Requirements for Living Donors

Proposal History

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) continually reviews donor-derived disease transmission events to identify opportunities to improve transplant safety.

Following investigations of recent donor-derived HIV and WNV transmission events, DTAC evaluated whether the existing donor infectious disease testing windows adequately protected transplant recipients from infections acquired shortly before organ recovery.

The Committee determined that the existing testing intervals—28 days for HIV and 14 days for WNV—could allow recently acquired infections to remain undetected despite compliance with OPTN policy.

Because additional transmissions could occur before completion of the standard policy development process, DTAC recommended that the OPTN Board of Directors approve these changes through its emergency policy authority.

The Board approved the recommendation on June 18, 2026 determining that immediate implementation was necessary to address an urgent patient safety concern.

Summary of Changes

- Reduce the required HIV NAT testing window from 28 days to 7 days prior to organ recovery.
- Reduce the required WNV NAT testing window from 14 days to 7 days prior to organ recovery.
- Continue to require testing to be performed as close as possible to organ recovery.

Implementation

Living donor recovery hospitals, organ procurement organizations, and transplant hospitals will need to update donor evaluation workflows and laboratory scheduling practices to ensure HIV and WNV are performed within the revised 7-day testing window.

Based on the implementation date of August 17, 2026 for WNV testing, WNV testing results must be available from within 7 days for all living donor donations that occur on or after August 24, 2026.

Affected Policy Language

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

Policy 14.4: Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

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 14-6 through 14-10 below.

Table 14-6: 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: a. Hypertension b. Diabetes c. Lung disease

This evaluation must be completed:	Including evaluation for and assessment of this information:
	d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support

This evaluation must be completed:	Including evaluation for and assessment of this information:
	• Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)

This evaluation must be completed:	Including evaluation for and assessment of this information:
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: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 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 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within ~~28 days~~ 7 days prior to organ recovery 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis B core antibody (total anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing

This evaluation must be completed:	Including evaluation for and assessment of this information:
	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*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA) For West Nile Virus (WNV), living donor recovery hospitals must test all potential donors with planned organ recovery between July 1st and October 31st for WNV by nucleic acid test (NAT), as close as possible, but within ~~14 days~~ 7 days prior to organ recovery. WNV test results must be obtained prior to organ recovery.
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: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer