OPTN

Public Comment Proposal

Require West Nile Virus Seasonal Testing for all Donors

OPTN Ad Hoc Disease Transmission Advisory Committee

Prepared by: UNOS Policy Department

Contents

Require West Nile Virus Seasonal Testing for all Donors

Affected Policies:	*2.9: Required Deceased Donor Infectious Disease Testing* *14.4: Medical Evaluation Requirements for Living Donors*
Sponsoring Committee:	*Ad Hoc Disease Transmission Advisory*
Public Comment Period:	*August 27, 2025 – October 1, 2025*

Executive Summary

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) proposes updates to OPTN Policy 2.9: *Required Deceased Donor Infectious Disease Testing* and 14.4: *Medical Evaluation Requirements for Living Donors* to require seasonal West Nile Virus (WNV) testing for all potential living and deceased donors. This proposal is in response to a recommendation from the Centers for Disease Control and Prevention (CDC), which advised the Committee to consider implementing seasonal WNV testing due to the significant risk that the virus poses to transplant recipients. The virus is associated with high morbidity and mortality rates for solid organ transplant and can be transmitted through organ transplantation and blood transfusion.[1] Most individuals living with WNV are asymptomatic, and no treatments or vaccines for WNV are currently available.[2] The virus is most active between the summer and fall months, making early detection through testing especially important during this period. Currently, WNV testing is not mandatory and is conducted voluntarily by Organ Procurement Organizations (OPOs) and living donor hospitals, leading to potential gaps in patient safety. This inconsistency increases the risk of undetected WNV transmission.

The Committee proposes mandatory living and deceased donor testing during the period of highest WNV activity, from July 1 to October 31. Testing during this defined seasonal window has a higher pre-test probability than other seasons, which reduces the likelihood of false positives and unnecessary organ non-use.[3] OPOs and living donor recovery hospitals would be required to conduct WNV testing using a nucleic acid test (NAT) that is Food and Drug Administration (FDA)-licensed, approved, or cleared. For living donors, NAT would have to be performed within seven days—or as close as possible—to the planned organ recovery date, with results available prior to organ recovery. For deceased donors, NAT results would be available before organ transplant. This approach ensures consistent screening during the months of highest WNV risk.

By mandating seasonal WNV testing across all OPOs and living donor hospitals, this proposal aims to reduce the risk of donor-derived WNV transmission, standardize testing practices, and improve transplant recipient safety and outcomes.

[1] West Nile and Organ Transplantation, Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/causes/organ-transplantation.html (Accessed May 21, 2025).
[2] West Nile: Symptoms, Diagnosis, and Treatment, Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/symptoms-diagnosis-treatment/index.html (Accessed May 21, 2025).
[3] Winston DJ, Vikram HR, et al, Donor-Derived West Nile Virus Infection in Solid Organ Transplant Recipients: Report of Four Additional Cases and Review of Clinical, Diagnostic, and Therapeutic Features. Transplantation. 97(9):881–889. doi: 10.1097/TP.0000000000000024 (Accessed July 8, 2025).

Purpose

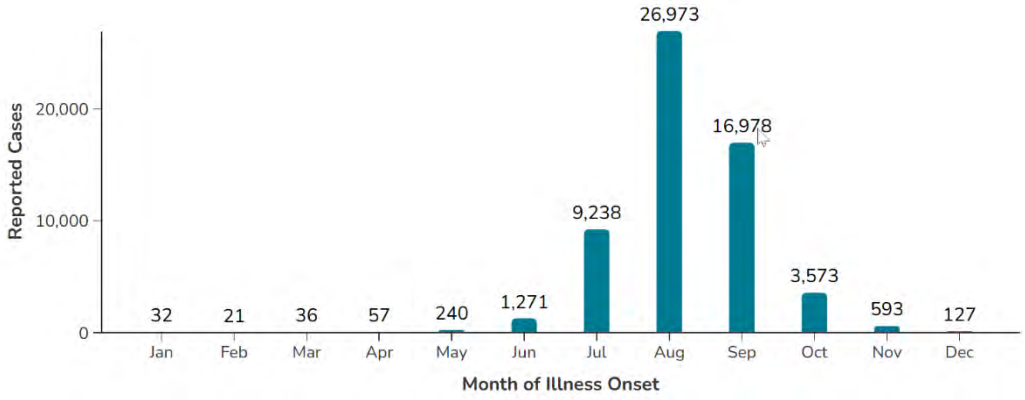
This project aims to improve patient safety by reducing the morbidity and mortality associated with West Nile Virus (WNV) transmission via solid organ transplantation by requiring seasonal WNV testing for potential deceased and living donors. Currently, OPOs and living donor hospitals are not required to routinely test donors for WNV, which can lead to unintended transmission of the virus to recipients and, in severe cases, result in death.[4] Additionally, individuals who have WNV are typically asymptomatic, and there is no treatment or vaccine for the virus, making it critical for donors to be tested for WNV prior to a recipient being transplanted. The Committee proposes updates to OPTN Policy 2.9: *Required Deceased Donor Infectious Disease Testing* and 14.4: *Medical Evaluation Requirements for Living Donors,* which will require OPOs and living donor hospitals to perform WNV testing on all potential living and deceased donors for WNV during the months of highest WNV activity, July 1 through October 31. The proposed updates will reduce the risk of donor-derived WNV transmission and improve overall transplant safety by requiring all OPOs and living donor transplant hospitals to test all potential donors for WNV in the predefined timeframe.

Background

West Nile Virus (WNV) is an arbovirus that belongs to the Flavivirus genus, a group of closely related species that share common ancestry and characteristics. WNV is the leading cause of arboviral disease in the United States and is most commonly spread to humans through the bite of an infected mosquito.[5] However, WNV can also be transmitted from person to person through organ transplantation and blood transfusion.[6] WNV is found in all 50 U.S. states, as well as parts of Europe, Africa, the Middle East, Asia, and Australia. The disease can lead to severe neurological complications, such as encephalitis—an inflammatory infection of the brain that can be fatal. From its introduction to the U.S. in 1999 to 2023, over 59,000 human cases and more than 2,900 deaths have been reported.[7] The virus is both geographic and seasonal, with cases typically occurring during mosquito season **(Figure 1)**, which typically spans from summer through fall in the U.S.[8]

[4] "About West Nile", Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/about/index.html (Accessed June 4, 2025).
[5] Ibid.
[6] West Nile and Organ Transplantation, Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/causes/organ-transplantation.html (Accessed May 21, 2025).
[7] "Historic Data (1999-2024), Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/data-maps/historic-data.html (Accessed June 20, 2025).
[8] Ibid.

Figure 1: West Nile virus human disease cases reported by month of illness onset, 1999-2023



The CDC collaborates with the Ad Hoc Disease Transmission Advisory Committee to consider issues related to the transmission of disease through organ transplantation and recommends policy and guidance documents to address these concerns. One such effort involved updating and consolidating four existing guidance documents into a single resource titled *Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation*, which was approved by the OPTN Board of Directors in December 2023.[9] This document includes specific guidance on identifying risk factors for WNV during the evaluation of potential living donors.

In October 2024, the CDC presented findings from an investigation of WNV transmissions by solid organ transplantation in the U.S. from 2002 to 2023, using data reported to ArboNET—a national arboviral surveillance system managed by the CDC and state health departments.[10] The investigation identified 11 confirmed clusters of WNV transmission through organ transplantation. Among the affected recipients, 87 percent showed evidence of WNV infection, 77 percent of those developed encephalitis, and 40 percent of those with encephalitis died as a result.[11]

The CDC recommended that the Committee consider implementing seasonal WNV testing requirements for all potential deceased and living donors, in alignment with CDC and FDA guidelines. To explore this recommendation, the Committee established the *Require West Nile Virus Seasonal Workgroup*, which included representatives from the OPTN OPO and Living Donor Committees, the CDC, and the FDA. The Workgroup discussed several key considerations: whether WNV testing should be mandatory for OPOs and living donor hospitals; defining a specific seasonal timeframe during which testing would be

[9] Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation, OPTN Ad Hoc Disease Transmission Advisory Committee, September 2023, https://optn.transplant.hrsa.gov/media/tjvptf3o/dtac_endemics-guidance_guidancedocument_pcsummer2023.pdf (Accessed June 4, 2025).

[10] ArboNet, Center for Disease Control and Prevention, https://www.cdc.gov/mosquitoes/php/arbonet/index.html (Accessed July 8, 2025).

[11] Sutter RA, Lyons S, Gould CV, Staples JE, Lindsey NP. West Nile Virus and Other Nationally Notifiable Arboviral Diseases — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:484–488. DOI: http://dx.doi.org/10.15585/mmwr.mm7321a2

required; determining the appropriate test to use for screening purpose; and establishing the timing for when test results should be available during the transplant process.

Overview of Proposal

The Committee proposes mandatory seasonal testing for WNV for all potential living and deceased organ donors. This proposal would require updates to OPTN Policy 2.9*: Required Deceased Donor Infectious Disease Testing* and Policy 14.4: *Medical Evaluation Requirements for Living Donors*. Under the proposed changes, OPOs and living donor hospitals would be required to test all potential donors for WNV between July 1 through October 31 using an FDA-licensed, approved, or cleared nucleic acid test (NAT).

For living donors, WNV NAT testing must be performed within seven days of the planned organ recovery—or as close to that date as possible—and results must be available prior to recovery. For deceased donors, WNV NAT test results must be available before organ implantation. These updates aim to establish a standardized, mandatory approach to WNV testing, replacing the current voluntary testing practices among OPOs and living donor hospitals. The goal of the proposed requirement to mandate WNV testing is to enhance transplant safety by detecting donor WNV infections that could be unexpectedly transmitted through transplantation.

Seasonal WNV Testing

There are several approaches to screening for WNV, including both seasonal and year-round testing. The Committee recommends adopting a seasonal testing strategy**,** within a pre-determined timeframe from July 1 through October 31. This timeframe aligns with the period of highest WNV activity in the U.S, typically observed during the summer through the fall months.[12]

This seasonal approach is consistent with CDC recommendations as data have shown that the majority of WNV cases are reported during these months.[13] Additionally, screening seasonally is more cost effective than testing year-round. Testing during this window is preferred because a higher pre-test probability during this period results in a lower likelihood of false positive results. Testing outside of peak WNV activity periods is more likely to yield false positive results, which could lead to unnecessary delays in transplantation or organ non-use. However, recognizing that some OPOs and living donor hospitals may test donors year-round on a voluntary basis, this proposed requirement would not preclude OPOs and living donor hospitals from continuing year-round WNV testing if it aligns with their current practices.

West Nile Virus Test Considerations

To screen for WNV, healthcare professionals may use NAT and immunoglobulin M (IgM) serologic tests.[14] The Committee proposes requiring a NAT test which directly detects the genetic material of the

[12] Historic Data (1999-2024), Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/data-maps/historic-data.html (Accessed July 2, 2025).
[13] Historic Data (1999-2024), Center for Disease Control and Prevention, https://www.cdc.gov/west-nile-virus/data-maps/historic-data.html (Accessed June 20, 2025).
[14] Recognizing Seasonal and Geographically Endemic Infection in Organ Donors: Considerations for Deceased and Living Donation, OPTN Ad Hoc Disease Transmission Advisory Committee, January 2024, https://optn.transplant.hrsa.gov/media/iiejup1b/optn-dtac_seasonal_endemic-infections_guidance.pdf (Accessed June 6, 2025).

WNV, with a positive result indicating the presence of the virus in the sample. In contrast, WNV IgM tests detect the body's immune response by assessing the presence of WNV IgM antibodies. While IgM is often a good indicator of a recent infection, there is a challenge with cross-reactivity. Cross-reactivity with IgM serologic test is of concern because WNV antibodies can react with other Flaviviruses due to shared structural similarities. This cross-reactivity can lead to misdiagnosis and can result in false-positive test results for WNV when a person has been infected with or vaccinated against a different Flavivirus.[15] Licensed NAT assays are highly specific; therefore, the false positive rate of NAT testing is expected to be very low particularly if testing is performed during peak WNV activity.[16]

The Committee further proposes that potential living donors are tested for WNV using an FDA-licensed, approved, or cleared NAT test within seven days of organ recovery, or as close to that date as possible, and NAT test results must be available prior to organ recovery. For deceased donors, the Committee proposes screening using an FDA-licensed, approved, or cleared test for WNV by NAT and test results must be available prior to implantation.

NOTA and Final Rule Analysis

The Committee submits this proposal under the authority of the National Organ Transplantation Act (NOTA), which states that the OPTN shall "adopt and use standards of quality for the acquisition and transportation of donated organs"[17] as well as under the authority of the OPTN Final Rule, which states the OPTN Board of Directors shall be responsible for developing "….policies, consistent with recommendation of the Centers for Disease Control and Prevention, for the testing of organ donors… to prevent the spread of infectious diseases."[18] This project will require all donors be screened for West Nile Virus to prevent the spread of infectious disease.

This proposal will also impact the collection of data. This data collection proposal is submitted under the authority of NOTA and the OPTN Final Rule. NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"[19] and the Final Rule requires the OPTN to "maintain records of all transplant candidates, all organ donors and all transplant recipients."[20] This proposal would collect data concerning organ donation in that it would require the reporting of all test results from all donors regarding their WNV status within the timeframe designated by the OPTN.

Implementation Considerations

Member and OPTN Operations

This proposal would impact organ procurement organizations, transplant hospitals, and the OPTN, but would not impact histocompatibility laboratories.

[15] Chen J, Padam C, Zayas V, Anthony P, Cormier J,.Cross-reactivity Between Powassan Virus and West Nile Virus in Patients with Encephalitis (P10-13.002) 102, no. 7 (2024) https://doi.org/10.1212/WNL.0000000000206587.
[16] "Identifying Risk Factors for West Nile Virus (WNV) During Evaluation of Potential Living Donors". Organ Procurement Organization for Transplant, https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/identifying-risk-factors-for-west-nile-virus-wnv-during-evaluation-of-potential-living-donors/ (Accessed June 20, 2025).
[17] 42 USC 274(b)(2)(E).
[18] 42 CFR Part 121.4(a)(2).
[19] 42 USC 274(b)(2)(I).
[20] 42 CFR Part 121.11(a)(ii).

Operations affecting Organ Procurement Organizations

Organ Procurement Organizations will be required to test all potential deceased donors between July 1 through October 31 for West Nile Virus using an FDA-licensed, approved, or cleared nucleic acid test (NAT), and NAT test results must be available before organ implantation. While the proposed policy states that NAT test results must be available before implantation, organ procurement organizations will be required to enter WNV NAT results into the OPTN Computer System at the time of electronic notification. During this period, the system currently includes a data field for WNV NAT results (allowing entries as positive, negative, not done, pending or indeterminate), which will be changed from an optional to a mandatory data field. However, before implantation, if a result was initially entered as not done or pending, organ procurement organizations will be required to update the result to positive, negative, or indeterminate to comply with the proposed policy. While the OPTN Computer System requires WNV NAT test results to be entered year-round, entry of NAT results will only be mandatory during the specified timeframe. Outside of the July to October timeframe, OPOs will still have to enter a response on WNV NAT test results, but it is acceptable to enter 'not done' and still be in compliance with policy if it is outside of the specified timeframe.

Operations affecting Transplant Hospitals

Living donor recovery hospitals will be required to test all potential living donors with planned organ recovery between July 1 through October 31 for WNV by nucleic acid test NAT, as close as possible, but within seven days prior to organ recovery, and will be required to have WNV NAT test results available prior to organ recovery. Transplant hospitals will have the option to enter NAT results into the OPTN Computer System on the living donor registration forms system as positive, negative, not done, or UNK/cannot disclose. If a result was initially entered as not done or pending, living donor recovery hospitals will be required to update the result to positive or negative to comply with the proposed policy. While the OPTN Computer System requires WNV NAT test results to be entered year-round, entry of NAT results will only be mandatory during the specified timeframe. Outside of the July to October timeframe, living donor recovery hospitals will still have to enter a response on WNV NAT test results, but it is acceptable to enter 'not done' and still be in compliance with policy if it is outside of the specified timeframe.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting the OPTN

For deceased donors, the OPTN will require data collection of a West Nile Virus NAT, a field which currently exists in the OPTN Computer System. Since this data collection field currently exists, no Office of Management and Budget (OMB) implications are anticipated. For living donors, the OPTN will implement a new West Nile Virus data collection field on the living donor registry form with response options within the OPTN Computer System. As this represents new data collection, it will require OMB approval, a process which may impact the implementation timeline for the living donor data collection. Thus, the OPTN system changes will be implemented in a phased approach, with efforts to implement deceased donor data changes directly following OPTN Board consideration, and living donor data changes subsequently following OMB review and approval.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Potential Impact on Select Patient Populations

The proposal will require WNV testing for all deceased and living donors. This proposal will improve patient safety for recipients by reducing unintended disease transmissions and deaths.

Projected Fiscal Impact

The Fiscal Impact Advisory Group, comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

Overall Project Fiscal Impact

The proposal was determined to have a low overall fiscal impact on the OPTN and transplant hospitals. Low fiscal impact was recorded for organ procurement organizations and no fiscal impact was recorded for histocompatibility labs.

Projected Impact on Organ Procurement Organizations

This proposal is not expected to have significant impact on OPOs. OPOs may have increased costs associated with compliance during seasonal testing, as well as staff training and education.

Projected Impact on Transplant Hospitals

This proposal is not expected to have significant impact on transplant hospitals. Transplant programs may have increased costs associated with compliance during seasonal testing, as well as staff training and education.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact on histocompatibility laboratories.

Projected Impact on the OPTN

It is estimated that $(redacted) would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the updated policy requirements and associated system tools. In addition, implementation would include building communications and education materials, updating process documents, and community outreach. It is estimated that $(redacted) would be needed for ongoing support. Ongoing support includes member support and education, compliance monitoring, system maintenance, and answering member questions as necessary. In addition, ongoing support will include a monitoring report

at the 1-year and 2-year timeframes. The total for implementation and ongoing support is estimated to be $(redacted).[21]

Post-implementation Monitoring

Member Compliance

The Final Rule requires that policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews."[22] During OPO and living donor hospital site surveys, an OPTN Contractor, on behalf of the OPTN, will review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, for documentation of either:

- Infectious disease testing using an FDA-licensed, approved, or cleared test for West Nile Virus by nucleic acid test (NAT) available prior to implantation for all deceased donor organ recoveries that occur between July 1 and October 31 or
- Infectious disease testing using an FDA-licensed, approved, or cleared test for West Nile Virus by nucleic acid test (NAT) within 7 days prior to organ recovery for all living donors that occur between July 1 and October 31.

Any data entered into the OPTN Computer System may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

This policy will be formally evaluated at approximately one- and two-years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data are available and sample size allows. Comparisons will be made pre- and post-policy when applicable.

- Volume of proven/probable West Nile Virus (WNV) potential donor-derived disease transmission events (PDDTE) submitted through the OPTN Computer System Improving Patient Safety Portal
- N (%) of donors recovered by donor type (deceased, living)
- N (%) of deceased donors with positive WNV NAT test results reported monthly for donors recovered during WNV required testing season (July 1 through October 31), and the associated overall distribution of WNV test results (positive, negative, not done, indeterminate/equivocal).
- N (%) of living donors with positive WNV NAT test results reported monthly for donors recovered during WNV required testing season (July 1 through October 31), and the associated overall distribution of WNV test results (positive, negative, not done, indeterminate/equivocal).

[21] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved. Resources estimates are exempted from public disclosure under the Freedom of Information Act exemption 4.

[22] 42 CFR §121.8(a)(7).

Conclusion

The Ad Hoc Disease Transmission Advisory Committee (the Committee) aims to update OPTN Policy 2.9: *Required Deceased Donor Infectious Disease Testing* and 14.4: *Medical Evaluation Requirements for Living Donors* to reduce unintended donor-derived transmission of WNV through organ transplantation. These updates would require OPOs and living donor hospitals to test all potential living and deceased donors for WNV during the months of highest WNV activity, July 1st and October 31st.

For living donors, NAT must be performed within seven days of the planned organ recovery—or as close to that date as possible—and results must be available prior to recovery. For deceased donors, NAT results must be obtained before organ implantation. These updates are intended to reduce WNV-related morbidity and mortality among transplant recipients by establishing a defined testing window. By doing so, the policy aims to prevent unintended WNV donor-derived transmission cases and enhance overall transplant safety.

Considerations for the Community

- Is the proposed requirement to have living donors tested for WNV within seven days or as close as possible to organ recovery an appropriate testing timeframe?

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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) 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

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

3. Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS CoV-2 (COVID-19) by nucleic acid test (NAT)

Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.

4. Infectious disease testing for all potential deceased donors for Strongyloides antibody, using either
   • an FDA licensed, approved, cleared, or Class 1, 510(k)-exempt test or
   • a Laboratory Developed Test (LDT), as described by the FDA.

5. Infectious disease testing for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the CDC at the time of testing. The OPTN maintains a list of countries currently classified as endemic for Chagas disease by the CDC. This testing must be performed using an FDA licensed, approved, or cleared donor screening test for T. cruzi antibody.

Within 72 hours of receipt of a positive T. cruzi antibody donor screening test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires either

- submission through the CDC or
- performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.

6. For potential deceased donors with planned organ recovery between July 1st and October 31st, infectious disease testing using an FDA licensed, approved, or cleared test for West Nile Virus by nucleic acid test (NAT)

NAT results for West Nile Virus must be available prior to implantation.

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.

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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 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 • 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*

This evaluation must be completed:	Including evaluation for and assessment of this information:
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 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 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) <u>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 7 days prior to organ recovery. WNV test results must be obtained prior to organ recovery.</u>

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: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer