Crosswalk between 2013 and 2020 US Public Health Service Guidelines and Current OPTN Policy[1]

Note: References to OPTN Policy are subject to updates based on ongoing review for consistency with the PHS Guidelines

Recommendation Category	2013	2020	Current OPTN Policy
Risk assessment of living and deceased donors	• OPOs should ascertain whether any of the following 14 risk criteria were present in potential organ donors.	• OPOs should ascertain whether any of the following 10 risk criteria were present in potential organ donors.	• *2.4 Deceased Donor Medical and Behavioral History* • *14.1.A Living Donor Medical Evaluation Requirements* Current policy requires the medical and behavioral/social assessments including whether the donor would meet "increased risk" designation under the PHS Guideline.
	Risk criteria (during the 12 months before organ procurement): 1. Sex with a person known or suspected to have HIV, HBV, or HCV infection 2. Drug injection for nonmedical reasons 3. Man who has had sex with another man 4. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours 5. Sex in exchange for money or drugs 6. Sex with a person who injected drugs for nonmedical reasons 7. Sex with a person who had sex in exchange for money or drugs 8. Unknown medical or social history 9. Child aged ≤18 months born to a mother known to be infected with or at increased risk for HIV, HBV, or HCV infection 10. Child who has been breastfed by a mother who is known to be infected with or at increased risk for HIV infection 11. Woman who has had sex with a man who has had sex with another man 12. Newly diagnosed or treated syphilis, gonorrhea, chlamydia, or genital ulcers 13. Hemodialysis 14. Hemodilution of the blood sample used for infectious disease testing	Risk criteria (during the 30 days before organ procurement): 1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection 2. Man who has had sex with another man 3. Sex in exchange for money or drugs 4. Sex with a person who had sex in exchange for money or drugs 5. Drug injection for nonmedical reasons 6. Sex with a person who injected drugs for nonmedical reasons 7. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours 8. Child breastfed by a mother with HIV infection 9. Child born to a mother with HIV, HBV, or HCV infection 10. Unknown medical or social history	• *1.2: Definitions:* *United States 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).* • *2.5 Hemodilution Assessment* Current policy requires members to use the 2013 PHS Guideline to determine if a donor is considered "increased risk".

[1] Adapted from TABLE 2. Comparison of 2013 and 2020 U.S. Public Health Service guideline recommendations* for solid organ donor assessment and transplant recipient monitoring for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection in Jones, JM, Kracalik, I, Levi, ME *"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"* MMWR Recomm Rep 2020;69 (7-8) available at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm.

This crosswalk is intended to assist transplant hospitals in comparing the 2013 PHS Guidelines and 2020 PHS Guidelines to current OPTN Policies. Use of this crosswalk is not an OPTN obligation and does not guarantee an assessment of compliance with OPTN obligations.

Recommendation Category	2013	2020	Current OPTN Policy
	• Donors with any risk criteria should be designated as IRDs for an acute HIV, HBV, and HCV infection.	• Remove any specific label (e.g., "increased risk donor") to describe donors with risk factors for acute HIV, HBV, and HCV infection.	Numerous OPTN policies and sections within reference and have requirements for "increased risk" donors: • *2.4 Deceased Donor Medical and Behavioral History* • *2.5 Hemodilution Assessment* • *2.7 HIV Screening of Potential Donors* • *2.9 Required Deceased Donor Infectious Disease Testing* • *13.11 Receiving and Accepting KPD Match Offers* • *14.4 Medical Evaluation Requirements for Living Donors* • *15.3 Informed Consent of Transmissible Disease Risk* • *16.2 Packaging and Labeling Responsibilities*
Living and deceased solid organ donor testing	• Test all potential organ donors (living and deceased) o HIV: anti-HIV-1/2 or HIV Ag/Ab combination assay o HBV: Anti HBc and HBsAg o HCV: NAT and anti-HCV • For IRD only, HIV NAT or HIV Ag/Ab combination	• Test all potential organ donors (living and deceased) o HIV: NAT and anti-HIV o HBV: NAT, anti-HBc, and HBsAg o HCV: NAT and anti-HCV	• *Policy 2.9 Required Deceased Donor Infectious Disease Testing* • *14.4.A Living Donor Medical Evaluation Requirements* Current policy allows HIV Ab/Ag testing. Current policy does not require HBV NAT testing. Current policy only requires either HIV NAT or HIV Ab/Ag testing on IRD donors.
	• No time frame is specified for pretransplant deceased donor testing; however, results should be available at the time of transplant.	• For deceased potential donors, the donor specimen should be collected within 96 hours before organ procurement with results of these screening tests available at the time of organ procurement.	• *Policy 2.9 Required Deceased Donor Infectious Disease Testing* Current OPTN policy does not have timelines for deceased donor infectious disease test collection or result availability.
	• Living donors should be tested within 28 days before transplantation.	• For living potential donors, testing should be performed as close as possible to the surgery but at least within the 28 days before organ procurement.	• *14.4.A Living Donor Medical Evaluation Requirements* Current policy matches the timing requirement.
Transplant candidate informed consent	• Transplant center to obtain separate, specific informed consent from transplant candidates when donors are designated as IRDs	• When donors with one or more of the criteria as specified under Risk Assessment of Living and Deceased Donors are identified, OPOs should communicate this information to the appropriate transplant centers. Transplant centers should include this information in informed consent discussions with transplant candidates or their medical decision-makers. No separate, specific informed consent is recommended. • Transplant centers should contextualize these discussions by including that risk for undetected HIV, HBV, and HCV infection is very low but not zero; should transmission occur effective therapies are available, and accepting organs from donors with risk factors might increase the chance for survival.	• *15.3.A General Risks of Potential Malignancy or Disease Transmission* • *15.3.B Donors with Risk Identified Pre-Transplant* Current policy requires informed consent for use of IRD donor and use of hemodiluted sample for infectious disease testing. The informed consent must be done after the organ offer but before transplant and the consent must be documented in the medical record.
Recipient testing and vaccination	• Pretransplant testing of transplant candidates for HIV, HBV, and HCV infections is recommended when the donor (living or deceased) is designated as IRD or infected with HBV or HCV. o Type of assay not specified o Timing: during hospital admission for transplant but before transplant	• Pretransplant testing for HIV, HBV, and HCV infections should be conducted for all recipients, regardless of donor risk criteria. o HIV: testing algorithm§ o HBV: anti-HBc, anti-HBs, and HBsAg o HCV: NAT and anti-HCV o Timing: During hospital admission for transplant but before transplant	• *15.2 Potential Candidate Screening Requirements* Current policy only specifies that candidates must have HIV, HBV, and HCV testing to be eligible for organ transplant. It does not specify testing type or more specific timing.

Recommendation Category	2013	2020	Current OPTN Policy
	• Posttransplant testing of organ recipients for HIV, HBV, and HCV infections should be conducted when the donor (living or deceased) is designated as IRD or infected with HBV or HCV. o Type of testing is not specified. o Timing: testing should be performed at 1–3 months posttransplant for HIV, HBV, and HCV and again at 12 months for HBV.	• Posttransplant testing for HIV, HBV, and HCV infections should be conducted for all recipients, regardless of donor risk criteria. o Type of testing: NAT for HIV, HBV, and HCV o Timing: 4–6 weeks posttransplant o Clinicians caring for liver recipients should maintain heightened awareness of the potential for delayed appearance of HBV infection and consider additional testing for HBV NAT at 1 year. o Recipients who develop signs or symptoms of liver injury after transplantation should be retested for viral hepatitis.	• *15.3 Recipients of Organs from Donors with Increased Risk of Disease Transmission* Policy does not contain specific timing or test type. It requires that the transplant program have a protocol for post-transplant testing of IRD organ recipients and to follow their own protocol. No current policy requirement exists for universal posttransplant testing (for all recipients).
	• No previous PHS guideline recommendation exists for HBV vaccination of transplant candidates.	• All organ transplant candidates should be vaccinated against HBV infection.	• No current OPTN policy exists
Collection and storage of donor and recipient specimens	• OPOs should consider archiving a deceased donor blood sample for 10 years.	• OPOs and living donor recovery centers should archive donor blood specimens for at least 10 years. These specimens should be collected within 24 hours before organ procurement.	• *2.2 OPO Responsibilities* OPOs are currently required to keep blood specimens for serology and NAT testing for 10 years. No OPTN policy requirement exists for living donor recovery hospitals and storage of blood specimens. .
Tracking and reporting of donor-derived disease transmission events	No recommendations in this category were substantially modified from 2013 to 2020.	No recommendations in this category were substantially modified from 2013 to 2020.	• *2.12 Post Procurement Follow Up and Reporting* • *15.1 Patient Safety Contact* • *15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions* • *15.5 Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy* • *15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy* OPTN policies require reporting of potential donor-derived disease transmission events. This includes blood-borne illnesses as well as other infections and malignancies.