

## ***Policy changes going into effect on September 1, 2016 for potential donor-derived disease transmission event reporting***

### **2.13 Post Procurement Follow Up and Reporting**

The host OPO is responsible for follow up and reporting of deceased donor test results received after procurement. The host OPO must develop and comply with written protocols to do all of the following:

1. Obtain and report all deceased donor test results to the OPTN Contractor
2. Report all positive test results and relevant information according to *Policy 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*
3. Report relevant test results and other information to tissue banks receiving donor tissue

### **15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions**

Host OPOs must report any test results or information received post-procurement that indicate there may be a possibility for donor-derived disease as follows.

#### **15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions**

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-1 below*.

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**Table 15-1: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions**

	The host OPO must report <i>all</i> of the following <i>positive</i> results:	To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: <ul style="list-style-type: none"> <li>• Ascites</li> <li>• Blood</li> <li>• Cerebrospinal fluid (CSF)</li> <li>• Deep wound</li> <li>• Genital</li> <li>• Pericardial</li> <li>• Pleural fluid</li> </ul>	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of <i>Candida</i> species	The receiving transplant program's patient safety contact
Relevant Information	Respiratory samples (bacterial or <i>Candida species</i> ) <i>only</i> to transplant programs receiving lungs or head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures (bacterial or <i>Candida species</i> ) <i>only</i> to transplant programs receiving kidneys or genitourinary VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
	All <i>final</i> culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

#### **15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy**

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program patient safety contacts and tissue banks that received organs, vessels, or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. The

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- host OPO must document that this information is shared with all receiving transplant programs and tissue banks.
2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

#### **15.4.C Host OPO Requirements for Post-Reporting Follow Up**

If the host OPO reports test results or other relevant information to the OPTN Contractor through the OPTN Improving Patient Safety Portal, then the host OPO must also do *all* the following:

1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal.
2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
3. Provide additional information or specimens related to the deceased donor if requested.

### **15.5 Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy**

Transplant programs must communicate any test results or information received post-transplant that indicate donor-derived disease is possible as follows.

#### **15.5.A Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy**

1. If the findings are from transplant program testing of the donor, then the transplant program must notify the host OPO or living donor recovery hospital of the findings.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the development of the disease or malignancy after transplant.
5. Offer the recipients additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.

#### **15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy**

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *all* of the following:

1. Notify host OPO or living donor recovery hospital that procured the organ without waiting for all medical documentation that may eventually become available. The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.

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### **15.5.C Transplant Program Requirements for Post-Reporting Follow-Up**

If the transplant program has a recipient that involved in an OPTN Improving Patient Safety Portal report, then the transplant program must also do *all* of the following:

1. Submit any relevant test results including cultures, infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
2. Respond to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding the recipient and communicate updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
3. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
4. Provide additional related information or specimens if requested.

## **15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy**

Living donor recovery hospitals must report any post donation test results or information that indicate there may be a possibility for donor-derived disease.

### **15.6.A Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy**

If a living donor recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the living donor recovery hospital must do *all* of the following:

1. Disclose to the living donor that the potential disease transmission or malignancy will be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal.
2. Notify the receiving transplant program.
3. Report the potential transmission through the OPTN Improving Patient Safety Portal as soon as possible but no more than seven days after receipt of the new information.

### **15.6.B Living Donor Program Requirements for Post Reporting Follow-Up**

If the living donor recovery hospital reports test results or other information to the OPTN Contractor through the Improving Patient Safety Portal, then the recovery hospital must also do *all* of the following:

1. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
2. Provide additional information or specimens related to the living donor if requested.

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**Policy changes going into effect after programming and member notification (Date to be determined) New policy is underlined. Policy that will no longer be in effect is in ~~strikethrough~~:**

## **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 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. Hepatitis B surface antigen (HBsAg) donor screening test
  - c. Hepatitis B core antibody (anti-HBc) donor screening test
  - d. Hepatitis C antibody donor screening test (anti-HCV)
  - e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
  - f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
  - g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
  - h. Syphilis donor screening *or* diagnostic test
  - i. 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.

### **2.11.C Required Information for Deceased Heart Donors**

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance
11. ~~Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital~~

For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

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