## Disease Transmission Event

**Improving Patient Safety**: Potential Donor-derived Disease Transmission Event

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and reduce the morbidity and mortality of transplant patients.

**Disease Transmission Event**:

All events involving unexpected, suspected or proven transmission of a medical condition, including infections and malignancies, discovered after procurement of a donor organ must be reported through the OPTN Patient Safety System.

**For OPO's**:

OPTN policy specifies when OPOs must report potential disease and malignancy transmission through this portal. OPOs must report the following to the OPTN:

- Results that indicate a disease or condition defined on Pathogens of Special Interest list
- Malignancy or other findings highly suggestive of malignancy recognized post-procurement
- Substantial concerns for donor derived disease or malignancy received from a transplant hospital

OPOs must also report these items within 24 hours, as well as others defined in policy, to transplant hospital patient safety contacts.

**For Transplant Programs**:

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, the transplant program must notify the Host OPO by phone and provide available documentation to the Host OPO as soon as possible, and not to exceed 24 hours of this knowledge/concern. The transplant center that suspects potential transmission should not wait for all medical documentation that may eventually be available, but must inform the Host OPO and the OPTN through the “Improving Patient Safety” portal, to transfer this knowledge/concern as soon as possible to all other centers that received organs from the same donor.

**For Living Donor Recovery Centers**:

When a transmissible disease or medical condition (including malignancy) is recognized in a living donor after organ procurement and relevant to acute patient care (defined as requiring clinical observation, diagnostic testing or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease), the center must notify the living donor transplant program and submit a report through the OPTN Improving Patient Safety Portal as soon as possible but no later than seven days after receipt of the new information.

Learn more about the required disease transmission event reporting in OPTN/UNOS policy.

Learn more about recent changes to this policy that changed on September 1, 2016

- Policy notice

- Webinar

Pathogens of Special Interest

To report a potential donor-derived disease transmission event, complete the information below and select the submit button. Please note the incidents are consider confidential and will only be viewable with member and patient identified entered by the user that initially submitted the information and UNOS staff.

## Event Information

**Reporting Event for:** This field is **required.**

**Donor (Living or Deceased)**
**Recipient**

**Donor ID:** The unique alphanumeric value assigned by the system when a donor is registered. This field is **required** if checkbox “Donor (Living or Deceased)” is selected.

**Have all of the recipient centers been notified at this time?:** This field is **required** if checkbox **“**Donor (Living or Deceased)” is selected.

**Yes**
**No**

**Recipient SSN:** The recipient’s social security number. Numeric format XXXXXXXXX. This field is **required** if Recipient is selected.

**Waitlist ID:** The system-generated number assigned after a candidate is added to the waiting list. Numeric format XXXXXXXX. This field is **optional** if Recipient is selected.

**Donor ID of donor involved:** The unique 6- or 7-character alphanumeric value assigned by the system when a donor is registered. This field is **required** if Recipient is selected.

**Has the Host OPO been notified regarding this report?:** This field is **required** if Recipient is selected.

**Yes**
**No**

**Reporting Institution**: Reporting member institution 4-digit code and name selected from the drop-down list. This field is **required**.

**Detected by**: This field is **required**.

**OPO before organs procured**
**OPO after organs procured**
**TX before organs procured**
**TX after organs procured**

**Date Occurred:** Date the disease transmission occurred. MM/DD/YYYY format. This field is **required.**

**Infection/Malignancy/Other Medical Condition:** More than one may be selected.

**Add Infection**
**Add Malignancy**
**Add Other Medical Condition**

## Add Infection

**Specify Type:** Values selected from a drop-down list. This field is **required**.

**Infection:** Value selected from a drop-down list. Up to four types may be selected. This field is **required**.

**Specify Type:**

**Amoebic**
**Bacterial**
**Fungal**
**Parasitic**
**Viral**

**Infection:**

**Encephalitis (All Types)**
**Endocarditis**
**Fever of Unknown Origin (FUO)**
**Meningitis (All Types)**
**Pneumoniae**
**Unknown Infection**
**Other Specify**
**Acinetobacter baumanii**
**AFB-other**
**Bacterial Emboli**
**Brucella**
**Citrobacter**
**E. coli**
**Ehrlichia**
**Endocarditis**
**Enterobacter asburiae**
**Enterococcus (not VRE)**
**Enterococcus (VRE)**
**Gram Positive Cocci (GPC)**
**Klebsiella**
**Legionnaires Disease**
**Listeria monocytogenes**
**Lyme Disease**
**Methicillin-resistant Staphylococcus aureus (MRSA)**
**Methicillin-sensitive Staphylococcus aureus (MSSA)**
**Mycobacterium Avium Complex (MAC)**
**Mycobacterium Kansaii**
**Mycobacterium (unknown)**
**Mycobacterium abscessus**
**Mycobacterium gordonae**
**Mycobacterium intracellulare**
**Mycoplasma hominis**

**Mycobacterium tuberculosis (TB)**
**Mycotic Aneurysm**
**Neisseria meningitides**
**Nocardia**
**Pneumoniae**
**Pseudomonas**
**Salmonella**
**Serratia**
**Staphylococcus**
**Streptococcus**
**Syphilis**
**Veilonella**
**Aspergillus**
**Blastomycosis**
**Candida albicans**
**Candida glabrata**
**Candida tropicalis**
**Candidiasis (unknown)**
**Cryptococcus**
**Coccidioides immitis (Valley Fever)**
**Histoplasma/Histoplasmosis**
**Rhizopus**
**Zygomycete**
**Amoebiasis**
**Babesia**
**Balamuthia mandrilli**
**Chagas (T.cruzi)**
**Leishmaniasis**
**Schistosomiasis**
**Strongyloides**
**Toxoplasmosis**
**Adenovirus**
**Cytomegalovirus (CMV)**
**Epstein-Barr virus (EBV)**
**Hepatitis B (HBV)**
**Hepatitis C (HCV)**
**Hepatitis E**
**Herpes Simplex Virus (HSV)**
**Human herpesvirus 8 (HHV8)**
**Human Immunodeficiency Virus (HIV)**
**Human T-cell lymphotropic virus I (HTLV-I)**
**Human T-cell lymphotropic virus II (HTLV-II)**
**Influenza A – H1N1**
**Influenza A (Not H1N1)**
**Lymphocytic Choriomenigitis virus (LCMV)**
**Parvo B19**
**PIV3 ParaInfluenzaVirus**
**Rabies**
**Rhinovirus**
**Viral Myocarditis**
**West Nile Virus (WNV)**

**Date Detected:** Date the infection was detected. MM/DD/YYYY format. This field is **required**.

**At this time the diagnosis is:** This field is **required**.

**Confirmed**
**Suspected**

**Add Malignancy**

**Malignancy:** Value selected from the drop-down list. Up to four types may be selected. This field is **required**.

**Adenocarcinoma**
**Adenocarcinoma Colon**
**Adenocarcinoma Prostate**
**Astrocytoma**
**Basaloid CA**
**Basal Cell**
**Bladder CA**
**Brain CA-Spindle Cell**
**Breast Cancer**
**Breast mass Bronchi-Aviolar CA**
**Cholangiocarcinoma**
**Chronic lymphocytic leukemia (CLL) Dermatofibrosarcoma Protuberans**
**Epithelioid Angiomyolipoma**
**Gastrointestinal stromal tumor (GIST)**
**Glioblastoma**
**Hepatocellular Carcinoma (HCC)**
**Kaposi's Sarcoma**
**Leukemia**
**Liposarcoma**
**Liver CA**
**Lung CA**
**Lymphoma Non-Hodgkins**
**Malignant T-cell Lymphoma**
**Medullablastoma**
**Melanocytic Lesion**
**Melanoma**
**Mesothelioma**
**Neuroendocrine CA**
**Non-Small Cell Carcinoma**
**Oncocytoma**
**Ovarian CA**
**Pancreatic CA**
**Paraganglioma**
**Pineoblastoma**
**Prostate Cancer**
**Renal Cell Carcinoma (RCC)**
**Sarcoma Squamous Cell CA**
**Small Bowel CA**
**Small Cell CA**
**Thyroid CA**

**Unknown CA**
**Urothelial Cell CA**
**Other Specify**

**Date Detected:** Date the malignancy was detected. MM/DD/YYYY format. This field is **required**.

**At this time the diagnosis is:** This field is **required**.

**Confirmed**
**Suspected**

**Add Other Medical Condition**

**Other Medical Condition:** Value selected from the drop-down list. Up to four types may be selected. This field is **required**.

**Amyloidosis**
**Creutzfeldt-Jakob Disease (CJD)**
**Hemochromatosis**
**Ornithine Transcarbamylase (OTC) Deficiency**
**Peanut allergy**
**Sarcoidosis**
**Other – Specify**

**Date Detected:** Date the condition was detected. MM/DD/YYYY format. This field is **required**.

**At this time the diagnosis is:** This field is **required**.

**Confirmed**
**Suspected**

**Please attach any relevant documents, including lab or diagnostic testing results:**
**Choose File:** To upload supporting documentation to the event form. This is **optional**. Maximum file upload size: 20 MB.

**Was an assay or other test used to identify organism disease?:** This field is **required**.

**Yes**
**No**
**Unknown**

**Add Assay/Test Type**

**Assay/Test Type**: This field is **required** if checkbox “Yes” is selected in response to “Was an assay or other test used to identify organism disease?”.

**Ab**
**Acid Fast Smear**
**Aerobic Cx**
**AFB Cx**

**BAL**
**Blood Cx**
**Bone Marrow Bx**
**Bronchial Bx**
**Bronchial Lavage**
**Bx**
**Cell block**
**Cell Ct & Diff**
**CMV Stain**
**CT of abd**
**CT of chest**
**CT of head**
**CT of pelvis**
**CXR**
**Cytology**
**DNA testing**
**FISH**
**Fluid Cx**
**Fungal Cx**
**Fungal stain**
**GMS stains**
**Gram stain**
**IgG**
**IgM**
**Legionella DFA & Cx**
**Molecular Fingerprinting**
**MRI of abd**
**MRI of chest**
**MRI of head**
**MRI of pelvis**
**NAT**
**PCR**
**Pneumocystic IFA**
**Pheumocystis Stain**
**PPD**
**Silver Stain**
**Smear**
**Sputum Cx**
**Surface Antigen**
**Urinalysis**
**Urine Cx**
**US of abd**
**US of pelvis**
**Viral Cx**
**RNA**
**Other – Specify**

**Results**: Value selected from drop-down menu. This field is **required** if checkbox “Yes” is selected in response to “Was an assay or other test used to identify organism disease?”.

**Positive**
**Negative**
**Indeterminate**
**Other**

**Date of test**: Date the test was completed. MM/DD/YYYY format. This field is **required** if checkbox "Yes" is selected in response to "Was an assay or other test used to identify organism disease?"

**Was the donor blood sample obtained pre or post transfusion?**: This field is **required** if checkbox "Yes" is selected in response to "Was an assay or other test used to identify organism disease?"

**Pre**
**Post**
**Unknown**

**What donor specimens remain for further testing? (Please indicate type and amount)**: A free-text field to describe specimens available for testing. 5000 character limit. This field is **required.**

**Was tissue recovered from this donor?:** This field is **required**.

**Yes**
**No**
**Unknown**

**Was an autopsy completed on this donor? (Please upload a copy of the autopsy report if available):** This field is **required**.

**Yes**
**No**
**Unknown**

**Have local/state public health authorities been contacted regarding this event? (If appropriate for nationally notifiable infectious diseases as defined by the US Public Health Services):** This field is **required**.

**Yes**
**No**
**Unknown**

**Enter narrative description of the event**: A free-text field to enter a detailed description of the event or to explain any other choices selected elsewhere on the form. 5000 character limit. This field is **required.**

## Contact Information

**Who is the patient safety contact at your institution for this event?**

**First Name:** First name of the institution's patient safety contact. 50 character limit. This field is **required**.

**Last Name:** Last name of the institution's patient safety contact. 50 character limit. This field is **required**.

**Phone contact (enter at least one): Office:** The office phone number of the institution's patient safety contact. Numeric format XXX-XXX-XXXX or XXXXXXXXXX. This field is **required**.

**ext.**: The extension of the office phone number. 10 character limit. This field is **optional**.

**Mobile:** The cell phone number of the institution's patient safety contact. Numeric format XXX-XXX-XXXX or XXXXXXXXXX. This field is **optional**.

**ext.**: The extension of the mobile number. 10 character limit. This field is **optional**.

**Email:** The email address of the institution's patient safety contact. 100 character limit. This field is **required**.

**Other contact info:** A free text field. 50 character limit. This field is **optional.**

**ext.**: The extension of the other contact info. 10 character limit. This field is **optional**.

**Person Submitting the Report:**

**First Name:** First name of the person submitting the report. 50 character limit. This field is **required**.

**Last Name:** Last name of the person submitting the report. 50 character limit. This field is **required**.

**Email:** The email address of the person submitting the report. 100 character limit. This field is **required**.

**Submit:** Select to submit form when entry is complete.

**Cancel:** Select to exit form before submitting an event. Any information entered on the form will be lost.

**Public Burden Statement:** The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection

Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.