

Transplant-Transmitted Infections **Instructions for State and Local Health Departments in use of the generic investigation form**

CDC developed this generic *Transplant-Transmitted Infections* form and instructions to assist state and local public health departments in the investigation and tracking of potential transplant-transmitted cases of infection. The form provides a broadly applicable framework for transplant investigations; for example, it includes tables for tracking and recording information about organ donors, organ recipients, diagnostic test results, and pertinent investigation contacts.

The form can be modified to suit the needs of the user and the particulars of the case at hand, and it can be used in combination with other applicable/available forms. For example, selected tables on the generic form could be used to supplement a disease-specific module.

Well-coordinated investigations among public health agencies, organ procurement organizations, transplant centers, clinicians, and laboratorians are strongly encouraged. CDC can be consulted regarding all aspects of diagnosing, treating, and investigating cases.

The form is largely self-explanatory; however, background and some instructions are provided below to assist in investigation and completing the form.

In the instructions, all page numbers refer to those in the form. The [Transplant-Transmitted Infection Task](#) list may be used in coordination with this form to ensure completion of relevant tasks in a timely manner.

Throughout the form, **approximate dates are acceptable (mm/yyyy)**, if precise dates are not available.

Investigation Process Background

Transplant-Transmitted Infections are recognized in several manners and often differ from standard public health protocols, in that, the CDC, via a working agreement with the Health Resources and Services Administration (HRSA) may be alerted to a potential transmission prior to local or state public health authorities. This unusual notification process is linked to the policies that govern transplantation in the United States which are described below. Despite these notifications, there have been many cases in which local and state health authorities recognize a potential transplant-associated transmission and begin investigation. This form and the information provided for its' use are meant to guide health departments that are participating in or leading investigations.

The U.S. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organ Transplant Act (NOTA) of 1984. The act called for a unified transplant network to be operated by a private, non-profit organization under federal contract. The United Network for Organ Sharing (UNOS) administers the OPTN under contract with HRSA. Under federal law, all U.S. transplant centers and organ procurement organizations (OPO) must be members of the OPTN to receive any funds through Medicare. A member directory can be located at: <http://optn.transplant.hrsa.gov/members/search.asp>.

All OPTN Members are subject to review and evaluation for compliance with OPTN policies; OPTN policy 4.5 (http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_16.pdf) requires reporting of suspected donor derived disease transmission in a recipient or new information regarding a



donor that indicates risk of disease transmission to recipients. Once notified, UNOS patient safety staff begins notifying transplant centers and requesting follow up on potentially impacted recipients. These reports are reviewed by UNOS's Disease Transmission Advisory Committee (DTAC) to determine the likelihood of transplant transmission, educate the transplant community, and inform policy. To ensure inclusion of appropriate public health authorities, CDC and HRSA created a working agreement. UNOS staff notifies CDC for cases that involve disease clusters, unknown diseases, or nationally notifiable diseases. Once public health begins investigation, UNOS will cease requests for information and recipient follow up. The agreement also requests that the reporting transplant center or OPO notify local public health authorities. CDC works first to establish recipient safety and then to determine residency of all involved; relevant health departments are notified promptly should a donor or recipient be within their jurisdiction. At completion of the investigation, a summary is provided to UNOS so that DTAC can assign a case classification and highlight important aspects of the case for the transplant community.

Public health departments have also recognized potential transplant-transmitted diseases. If such an investigation is initiated, encouragement should be given to the relevant organization (transplant center or OPO) to report to UNOS. This ensures timely notification of other organ recipients, tissue banks, and eye banks.



Transplant-Transmitted Infections Data Collection Form Instructions

Pages 1-2

Organism / Disease Involved: Specify the reported pathogen / illness recognized in organ recipient or organ donor. If the disease presents as an unknown cluster / unknown illness list as 'unknown'.

Organism / Disease Identified in: Indicate the patient (organ donor or recipient) in whom the disease was first recognized and reported.

Local ID: health department assigned ID for the case.

OPO Information / Donor Information p.1

UNOS ID #: UNOS uses unique identification numbers for each donor. The reporting transplant center or OPO normally have access to this number. This number can be used to link a donor with organ recipients and can also identify the donor to the tissue bank and eye bank. It can be used when contacting other transplant centers, tissue banks, and eye banks so that these centers can identify recipients or products from the organ donor involved in the investigation.

OPO Name: Name of the organ procurement organization that procured and distributed organs from the involved organ donor.

Contact Name: The contact person at the OPO. May include the medical director or a director of quality.

City, State, Office Phone, Cell Phone, E-mail address: Contact information for the OPO and specific OPO contact involved.

Donor Hospital, City, State, Contact Name, Office Phone, Cell Phone, e-mail: Hospital information regarding the facility that took care of organ donor during terminal hospitalization and contact at that hospital. This hospital may have access to specimens from donor, records and testing pertaining to terminal hospitalization, autopsy reports / specimens, and blood product transfusion records given to the donor prior to organ procurement.

Donor Demographics: To facilitate donor investigation, provide whatever basic demographic information is available, in accordance with privacy protection laws and public health purpose for this information. Record **name** (or another unique identifier), **address**, contact information, and **date of birth** (or mm/yyyy). Indicate the donor's **age** at the time of donation, **sex**, and **ethnicity**. For **race**, select all that apply.

Diagnostic Test(s) used to detect Organism / Disease: Record information regarding testing used to detect disease in the index patient (*may be organ donor or recipient*).

Brief description of event: Describe how the disease was diagnosed or recognized in the organ donor or recipient reported on page 1.

Date organs recovered: the date that organ procurement took place.



The information below can often be found on a form called the *Potential Disease Transmission Report (PDTR)* which will also include contact information for all involved transplant centers. This form is required by UNOS from the OPO for cases reported to UNOS patient safety. In some cases, the OPO will have the form filled out and can send to the investigating health department. In cases that have not been reported to UNOS, they will not have the information and may have to report verbally to the health department.

Check organs recovered: check all organs that were recovered from the organ donor.

Transplanted: Indicate if organs were transplanted (organs may be discarded, not recovered, or used for research).

Transplant center notified: indicate if the transplant center was notified of the potential transplant-transmitted infection.

Was an autopsy performed: The OPO will generally know this information, but may also ask the donor hospital if an autopsy was completed. If tissues were procured, investigators may also ask the tissue bank as the OPO may be unaware of an autopsy completed post-organ procurement if the organizations are separate.

Are donor specimens available for testing: May ask the OPO about donor stored serum (required to be stored for 10 years per OPTN policy), tissues used for HLA typing (spleen and lymph node), and autopsy specimens. There are instances in which the OPO will send donor serum to transplant centers along with the donated organ. Spleen and lymph node tissue may be found in the OPO's HLA lab or at individual transplant centers' HLA labs.

If yes, were blood products given prior to death, results of hemodilution calculations: If blood products and fluids were given in the 24 hours prior to sample collection, the OPO will perform hemodilution calculations. These calculations are used to indicate if the testing performed can be relied on to accurately reflect the status of the organ donor rather than the status of the transfused products. For example, if a hepatitis C *positive* organ donor receives a large amount of blood products and a serum sample is drawn shortly after infusion, the subsequent hepatitis C test done on that sample may come back *negative*. This negative test is actually reflecting the hepatitis C negative blood products that the donor received rather than the true status of the organ donor. The OPO can provide the hemodilution calculations. Regardless of hemodilution calculation results, you may want to consider blood product transfusion investigation if it is possible that the organism in question was transmitted via transfusion to the donor.

Donor specimens at the OPO: indicate if the OPO has **serum** stored and the available quantity. Indicate if any **tissues** are available at the OPO (HLA labs or other areas) and list all specimens.

Donor specimens at donor hospital and/ or transplant center(s): indicate if the donor hospital or any transplant center has **serum** stored. List the contact at each center and the available quantity. Indicate if any **tissues** are available (HLA labs or other areas) and list all specimens. Consider liver and kidney biopsy performed prior to organ procurement at the donor hospital.

Were tissues procured: indicate whether tissues or cornea were recovered from the donor. If so, notification of tissue and/or eye banks should be considered to facilitate contact and follow up of tissue recipients.

Donor autopsy specimens: Indicate if autopsy specimens are available. List the pathology contact to obtain specimens. List all specimens.

Transplant Recipient Hospital(s) Information p.4

For each organ recipient (each organ transplanted into a different recipient) complete a separate page. The same page may be used in cases where multiple organs are transplanted into the same recipient (i.e. double lung, kidney/pancreas).



Organs Transplanted: Indicate the organ transplanted into the specific recipient. If the recipient obtained more than one organ from the donor check all that apply (i.e. a bilateral lung recipient would have received both the right and left lung).

Transplant hospital, Contact name, Office Phone, Cell Phone, E-mail address: List the transplant hospital center / name, location, point of contact's name, title, phone numbers and e-mail address.

Recipient Demographics: To facilitate further recipient investigation provide whatever basic demographic information is available, in accordance with privacy protection laws. Record **name** (or another unique identifier), **address**, **contact information**, and **date of birth** (or mm/yyyy). Indicate the recipient's **age**, **sex**, and **ethnicity**. For **race**, select all that apply.

Does the organ recipient have clinical or laboratory evidence consistent with implicated disease: indicate if the recipient is suspected of having had the infection or has an illness consistent with the infection in question.

If yes, describe: describe the clinical presentation, signs, symptoms, and / or hospital course and any pertinent treatment / testing.

Diagnostic testing: Testing specific for the pathogen in question. List the information requested for any testing performed.

Did organ recipient receive blood product: Depending on the pathogen may need to consider blood as a potential source of infection.

Tissue/ cornea Investigation p.6

Indicate if tissues/ corneas were procured from the donor: If tissues/ corneas were procured then the status of the tissues should be investigated; they may be implanted, destroyed, quarantined, sent for research, or distributed to hospitals.

Tissue bank and Eye bank information: Record location and contact information for each pertinent bank type.

Check if Tissues were recovered: Indicate disposition by checking the appropriate box. This is a general guide as one organ donor may have hundreds of tissue products obtained (skin, tendon, bone, vascular tissue, heart valves, etc). If it is decided that a full tissue investigation should occur due to disease transmissibility risk via tissue, then a separate tracking form will need to be used to track each tissue type and place to which it was distributed. Tissue nomenclature is not standardized so a generic EXCEL spreadsheet should be used with the following suggested headings:

- Tissue identification number (assigned by the tissue bank)
- Tissue name / type (tissue bank assignment)
- Processing (discuss with the tissue bank the type of tissue processing used; this will depend on the type of tissue as well as the individual bank processes. For example, bone may be irradiated while a heart valve has an antibiotic wash).
- Center / hospital/ physician receiving tissue
- Tissue outcome (implanted, destroyed, quarantined at tissue bank)
- Date implanted/destroyed / quarantined (mm/dd/yyyy)
- Tissue recipient status that received implant (i.e. notified and well)
- Tissue recipient testing (if indicated)

Tissues available for testing: Indicate if the tissue bank has tissues available for testing and list tissues that are available.



Notes: use for additional notes on the investigation.

