Safety Situation

Safety Situation:

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 decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?:

A situation or activity that affected or could have affected patient safety.

What to report:

Transplant hospitals must report the following events within 72 hours of becoming aware of the event:

- A transplant of the incorrect organ into an organ recipient occurs
- A transplant of an organ into the incorrect organ recipient occurs
- A donor organ is identified as incorrect during pre-transplant processes conducted according to either OPTN Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt or OPTN Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either OPTN Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt or OPTN Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either OPTN Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt or OPTN Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt

OPOs must report the following events within 72 hours of becoming aware of the event:

- Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required
- An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in OPTN Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype, and after the OPO has executed a match run

In general:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective

Please report such situations in a timely manner.

To report a safety situation, complete the information below and select the Submit button. Please note that incidents are treated as confidential information. The identities of the reporter and reporting institution will only be available to UNOS staff and are protected by the medical peer review process.

Situation Information

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

Recipient/Candidate: Selected if the event being reported involved a recipient or candidate.

Waitlist ID: Enter the recipient/candidate waitlist ID number. 8 digit numeral format. This field is **required** when checkbox “Recipient/Candidate” is selected and no SSN is provided.

Donor Organ/Extra Vessels: Selected if the event being reported involved a donor.

Donor ID associated with the event: If Donor Organ/Extra Vessels is selected, the donor ID is **required.** The donor ID is the unique 6-7 character alphanumeric value assigned by the system when a donor is registered.

Other (please describe in the description field below): Select only. No additional options.

Date Event Occurred: Date the safety situation event occurred. MM/DD/YYYY format. This field is **required**.

Detailed 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.**

Has a root cause analysis (RCA) been completed?: This field is **required**.

Yes
No
In Progress

Please specify additional details regarding the RCA: A free-text field to indicate whether a root cause analysis has been completed. 5000 character limit. This field is **required.**

Contact Information

Who at your institution should the OPTN contractor contact about this case?

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

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

Phone contact (Enter at least one) Office: The office phone number of the institution's 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. Alphanumeric 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.

Submit: Select to submit form when entry is complete.

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.