

# Safety Situation Field Descriptions

## **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 effected patient safety.

## **What to report:**

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

## **Please report such situation 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**.

**Type of Safety Event (Choose all categories and subcategories that are applicable):** At least one category must be selected. This field is **required**. (Values: Communication, Data Entry, Transportation, Packaging/Shipping, Labeling, Recovery Procedure/Process, Transplant Procedure/Process, Testing, Organ Allocation/Placement, Other (please describe in description field below))

**The issue reported involved the following (choose all categories that are applicable):** This field is **required**. (Values: Recipient/Candidate, Donor organ/extra vessels, Other (please describe in the description field below))

**Communication:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: Hand off Error, Miscommunications of donor test results, Miscommunication of recipient/candidate results, Change in test results not reported, Misinterpretation of test results, Delayed communication, Reliance on electronic instead of verbal communication, Inaccurate/insufficient donor or (organ/extra vessels) information, Inaccurate/insufficient candidate/recipient information, Missing documentation, Increased risk (or high risk) status of donor, Patient not informed adequately (or not informed at all), Other (please describe in the description field below))

**Data Entry:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: DonorNet<sup>®</sup>, Waitlist<sup>SM</sup>, Other (please describe in the description field below))

**Data Entry - DonorNet<sup>®</sup>:** An additional selection is **required** if the DonorNet<sup>®</sup> subcategory is selected. More than one option may be selected. (Values: Donor ID, Demographics (e.g., height, weight, ethnicity), ABO, ABO Subtyping, HLA, Labs (e.g., creatinine, INR), Infectious disease test result(s), Increased risk (or high risk) status of donor, Other (please describe in the description field below))

**Data Entry - Waitlist<sup>SM</sup>:** An additional selection is **required** if the Waitlist<sup>SM</sup> subcategory is selected. More than one option may be selected. (Values: Donor ID, Demographics (e.g., height, weight, age, ethnicity), ABO, ABO Subtyping, HLA, Labs (e.g., creatinine, INR), Donor acceptance criteria, Inaccurate patient priority status, Patient removed or inactivated in error, Other (please describe in the description field below))

**Data Entry - Other:** Select only. No additional subcategories.

**Transportation:** A subcategory selection is **required** if the parent category is selected. More than one option may be selected. (Values: Airline (commercial), Airline (charter/private), Ground, Other (please describe in the description field below))

**Transportation - Airline (commercial):** An additional selection is **required** if the Airline (commercial) subcategory is selected. More than one option can be selected. (Values: Airline misdirected, Weather, Mechanical delay/cancellation, Airline refused transport, Missed flight, Failure to board organ at airport, Failure to offload organ at airport, Other (please describe in the description field below))

**Transportation - Airline (charter/private):** An additional selection is **required** if the Airline (charter/private) subcategory is selected. More than one option may be selected. (Values: Airline misdirected, Weather, Mechanical delay/cancellation, Airline refused transport, Missed flight, Failure to board organ at airport, Failure to offload organ at airport, Other (please describe in the description field below))

**Transportation – Ground:** An additional selection is **required** if the Ground subcategory is selected. More than one option may be selected. (Values: Weather, Traffic, Courier/driver, Other (please describe in the description field below))

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

**Packaging/Shipping:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: Not packaged according to requirements, Switched laterality for Packaging/Shipping, Kidneys, Split Liver, Lungs, Wrong organ sent (e.g., liver sent instead of kidney), Insufficient or missing blood/nodes/spleen, Correct type of organ (or vessel), but from wrong donor, Ice melted, Frozen organ, Preservation fluid issue, Diagnostic materials from wrong donor, Container/bag not properly closed, Other (please describe in the description field below))

**Labeling:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: ABO, Donor ID, Required information missing, Transcription error, Switched laterality for Labeling, Incorrect test results, Blood/nodes/spleen labeling issue, Missing label, Other (please describe in the description field below))

**Recovery Procedure/Process:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: OR suite unavailable, OR time delayed, Injury to organ or vessels, Sterile field breach or other sterility issue, Equipment malfunction, Retained surgical instrument, Preservation fluid issue, Organ not cleaned well, Organ not properly inspected, Poor donor management, Issue with recovering transplant team(s), Other (please describe in the description field below))

**Transplant Procedure/Process:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: OR suite unavailable, OR time delayed, Direct injury to organ, Equipment malfunction, Retained surgical instrument, Wrong organ transplanted, Wrong laterality transplanted, Sterile field breach, Insufficient surgical coverage, Donor/recipient compatibility check not performed, Vessels used in a non-transplant patient, Other (please describe in the description field below))

**Testing:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: ABO, HLA, Infectious Disease, Other (please describe in the description field below))

**Testing - ABO:** An additional selection is **required** if the ABO subcategory is selected. More than one option may be selected. (Values: ABO error or discrepancy, ABO misinterpretation, ABO subtyping error or discrepancy, ABO subtyping misinterpretation, Blood transfusion caused misleading results, Switched samples, Switched source documentation, Inadequate sample for testing, Other (please describe in the description field below))

**Testing - HLA:** An additional selection is **required** if the HLA subcategory is selected. More than one option may be selected. (Values: False Negative cross-match, False Positive cross-match, Inadequate sample for testing, Required test not used, Wrong type of test used, Discrepant results, Switched samples, Inaccurate results reported, Other (please describe in the description field below))

**Testing - Infectious Disease:** An additional selection is **required** if the Infectious Disease subcategory is selected. More than one option may be selected. (Values: Hemodilution error or discrepancy, Infectious disease test results not available prior to match run, Infectious disease test results not available prior to transplant, Cultures not available or not done, Important or required test(s) not done, Required test not used (other test used instead), Wrong type of test used (e.g., diagnostic instead of screening), Switched samples, Discrepant results, Other (please describe in the description field below))

**Testing - Other (Please describe in the description field below):** Select only. No additional subcategories.

**Organ Allocation/Placement:** A subcategory selection is **required** if the parent category is selected. More than one subcategory may be selected. (Values: Offer rescinded, Offer not made to secondary contact, Out of sequence allocation, Inaccurate patient priority or status, Recipient not on match run, Inaccurate donor data caused match to run incorrectly, Match not rerun once serology found to be positive, Other (please describe in the description field below))

**Other (please describe in description field below):** Select only. No additional subcategories.

**The issue reported involves the following (choose all categories that are applicable):**

**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.

**SSN:** The recipient/candidate social security number. XXXXXXXXX numerical format. This field is **required** if checkbox "No Waitlist ID" is selected and no Waitlist ID 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.

**Did this event involve the entire donor or were only specific organs involved?** This field is **required** when checkbox “Donor Organ/Extra Vessels” is selected. (Values: Entire Donor, Specific Organs)

**Organ Type:** At least one organ must be selected from the list when checkbox “Specific Organs” is selected. (Values include: Right Kidney, Left Kidney, Dual/En-bloc Kidney, Pancreas, Pancreas Segment 1, Pancreas Segment 2, Liver, Liver Segment 1, Liver Segment 2, Intestine, Intestine Segment 1, Intestine Segment 2, Heart, Right Lung, Left Lung, Double/En-bloc Lung, Extra Vessel(s))

**Did this safety situation cause or contribute to:** the non-recovery of organ(s)? (Values: Yes, No, Unknown)

**The discard of any organ(s)?** (Values: Yes, No, Unknown)

**A delay (prolonged ischemic time) for any organ(s) transplanted?** (Values: Yes, No, Unknown)

**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?** (Values: Yes, No, In Progress). This field is **required**.

**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 XXXXXXXXXXX. This field is **required**.

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

**Pager/Beeper:** The pager/beeper number of the institution’s patient safety contact. Numeric format XXX-XXX-XXXX or XXXXXXXXXXX. This field is optional.

**ext.:** The extension of the pager/beeper 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 XXXXXXXXXXX. 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.