

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**.

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**.

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.

- 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[®]
- WaitlistSM
- Other (please describe in the description field below)

Data Entry - DonorNet[®]: An additional selection is **required** if the DonorNet[®] subcategory is selected. More than one option may be selected.

- 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 - WaitlistSM: An additional selection is **required** if the WaitlistSM subcategory is selected. More than one option may be selected.

- 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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

- 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.

- Entire Donor**
- Specific Organs**

Organ Type: At least one organ must be selected from the list when checkbox "Specific Organs" is selected.

- 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)?

Yes
No
Unknown

The discard of any organ(s)?

Yes
No
Unknown

A delay (prolonged ischemic time) for any organ(s) transplanted?

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?: 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 XXXXXXXXXXXX. 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 XXXXXXXXXXXX. 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 XXXXXXXXXXXX. 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.