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**.

<u>Type of Safety Event (Choose all categories and subcategories that are applicable)</u>: 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)

<u>Communication</u>: 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)

<u>Data Entry</u>: 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)

<u>Data Entry - DonorNet</u>[®]: 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)

<u>Data Entry - Waitlist</u>SM: 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.

<u>Transportation</u>: 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)

<u>Transportation - Airline (commercial)</u>: 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)

<u>Transportation - Airline (charter/private)</u>: 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)

<u>Transportation – Ground</u>: 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)

<u>Transportation - Other (please describe in the description field below)</u>: 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 Lunas

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)

<u>Labeling</u>: 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)

<u>Transplant Procedure/Process</u>: 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)

<u>Testing - HLA</u>: 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)

<u>Testing - Infectious Disease</u>: 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)

<u>Testing - Other (Please describe in the description field below)</u>: Select only. No additional subcategories.

<u>Organ Allocation/Placement</u>: 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. XXXXXXXX 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.

<u>Did this event involve the entire donor or were only specific organs involved?</u>: 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)

<u>Did this safety situation cause or contribute to</u>: 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.

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

<u>Detailed description of the event</u>: 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

<u>Please specify additional details regarding the RCA</u>: 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.

<u>Phone contact (Enter at least one) Office:</u> The office phone number of the institution's contact. Numeric format XXX-XXX or XXXXXXXXX. This field is **required**.

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

<u>Pager/Beeper</u>: The pager/beeper number of the institution's patient safety contact. Numeric format XXX-XXX-XXXX or XXXXXXXXXX. 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 XXXXXXXXX. 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.