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| ***Report Type*** |  ***Who reports?*** | ***What to report?*** | ***How to report?*** |  ***Information to include*** |
| **Disease Transmission****Events****\* required per OPTN****policy 15.4** | Any OPTNmember OPO, living donor recovery hospital, or transplant program | Any time an organ recipient is:* suspected to have,
* is confirmed positive for, or
* has died from a potential transmissible disease or medical condition (including infections and malignancies) and there is concern that it could be from

the transplanted organ.  | Events must be reported through the Improving Patient Safety portal within 24 hours of knowledge of the event. Access Secure Enterprise at <https://portal.unos.org>. Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates - **Disease Transmission Event**. Complete the information on the screen and select the submit button. *Please note:* Reported transmissions are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report. | Information required:* Donor ID or recipient SSN
* Recipient status
* Suspected or proven disease or disorder
* Date and method of detection
* Planned course of follow-up testing and treatment

Include all case specific details to give UNOS staff a full understanding of the situation. |
| **Living Donor Adverse****Events****\* required per OPTN****policy 18.5** | Any OPTNmember living donor recovery hospital  |  Any time instances occur of :* Living donor death within two years of donation
* Failure of the living donor’s remaining organ function identified within two years of donation.
* Living donor organs recovered but not transplanted
* Living donor organs recovered and transplanted into someone other than intended recipient
 | Events must be reported through the Improving Patient Safety portal within 72 hours of knowledge of the event. Access Secure Enterprise at <https://portal.unos.org>. Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates- **Living Donor Adverse Event**. Complete the information on the screen and select the submit button. *Please note:* Reported events are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report. | Information required:* Donor ID and SSN,
* Type of event,
* Date of event and knowledge of event
* Institution reporting

Include all case specific details to give UNOS staff a full understanding of the situation. |
| **Allocation Issues or****Concerns** | Any OPTNmember OPO, transplant program, or lab | Any time a recognized potentialviolation of OPTN/UNOS policies, bylaws or OPTN Final Rule occurs at any member institution related to organ allocation. | The following options are for reporting allocation issues,concerns, or self-reports (based on access to SecureEnterprise).• Mail - UNOS Department of Evaluation & Quality 700 North 4th St.  Richmond, VA 23219• Fax - 804-782-4680  Attention: Quality Assurance Analyst• Secure Email to your Regional Quality Assurance Analyst or Matt Belton, Manger, Allocation Analysis and Quality Inspection (matt.belton@unos.org)   | Suggested information: * Donor ID
* Organ type
* Contributing factors
* Timeline of events Dates/times
* Institution names
* Names of those involved
* Impact to patient(s)

Include all case specific details to give UNOS staff a full understanding of the situation. |

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| ***What to report?*** |  ***Who reports?*** | ***When to report?*** | ***How to report?*** |  ***Information to include*** |
| **Member Concerns** | Any OPTN member OPO, transplant program, or lab | When an individual wishes to anonymously report a concern or inform UNOS of any potential policy or bylaw violation at a member institution(s). | By phone: OPTN member reporting line at 866-787-4909 UNOS staff monitor the reporting line from8:30 a.m. to 5:00 p.m. (EST) Monday through Friday, and maintains confidentiality to the extent permitted by law. After business hours, calls are forwarded to a voice messaging system that is monitored to address matters needing immediate attention. *Please Note*: This avenue of reporting is an option for members who do not wish to be identified and/or those that do not have access to Secure Enterprise. | Suggested information:* Donor ID
* Timeline of events
* Dates/times
* Institution names
* Names of those involved
* Impact on patient(s)

Include all case specific details to give UNOS staff a full understanding of the situation. |
| **Patient Concerns** | Any patient,family member, friend, potential donor and/or medical professional | Any time patients have questions or concerns about transplantation, the donation process, living donation, or the various center-specific data reports provided on the public website. | By phone: OPTN patient services reporting line at888-894-6361 Patient Services staff monitor the reporting line from 8:00 a.m. to 4:00 p.m. EST, Monday through Friday. Patients may also send an email to staff via the Transplant Living or UNOS websites at the links below. <http://www.transplantliving.org/community/contact-us/><http://www.unos.org/contact/index.php> | Information to include: * First Name, Last Name
* Contact information (phone/email)
* Type of Question/Concern
* Living Donation
* Organ Allocation Policy
* Patient Information
* Support Groups
* Technical Issue
* Waitlist
* Website content
 |
| **Patient Safety****Situations** | Any OPTNmember: OPO, transplant center, or lab | Any time an event occurs that represents a specific and time-sensitive risk to patient health and public safety at OPTN institutions, which may include: near misses, policy and protocol related deficiencies and deviations, quality of care concerns, or inequitable patterns of behavior by any members. | Events should be reported through the Improving Patient Safety portal – access Secure Enterprise at <https://portal.unos.org>. Click on the tab to the right of the home screen labeled “Improving Patient Safety.” Select the radio button that indicates - **Safety Situation**. Complete the information on the screen and select the submit button. *Please note:* Reported events are considered confidential and can only be *viewed* within the system by UNOS staff and the user that submits the report.  | Suggested information: * Donor ID,
* Timeline of events,
* Dates/times,
* Institution names,
* Names of those involved
* Impact on patient(s)

Include all case specific details to give UNOS staff a full understanding of the situation. |