



## Proposal at a glance

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**Public Comment Proposal:** Modify Data Submission Policies

**Sponsoring Committee:** OPTN Data Advisory Committee

**You may be interested in this proposal if:**

- You work for an OPO
- You work for a histocompatibility lab
- You work for a transplant hospital

**Here's what we propose and why:**

We propose changing the process for submitting data to allow for more accurate collection by extending the timelines for data submittal. In order to change data following the submission deadline, members will need to provide the following information in the data system:

1. Indicate why data are changing
2. Obtain approval from organizational leadership to make changes, and submit the approver's name

This proposal is being driven by the goal of having the most accurate, high-quality data at the time of entry.

**Why this may matter to you:**

These actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement. High-quality data will also improve the policy development activities and evaluation of transplant system performance. Additionally, other researchers who study and assess transplant system performance will benefit from data quality improvements. It also aligns with regulations that require timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs.

**Tell us what you think about:**

- What are the most common reasons your organization changes data values after they have been officially submitted?
- What circumstances or conditions prevent your organization from submitting accurate data within the current deadlines?
- In addition to what is currently available, what data quality resources or electronic tools would help your organization ensure data are submitted accurately and within the established timeframes?

## Public Comment Proposal

# Modify Data Submission Policies

*OPTN Data Advisory Committee*

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# Modify Data Submission Policies

<i>Affected Policies:</i>	<i>Policy 18.1: Data Submission Requirements; Policy 18.4: Data Submission Standard</i>
<i>Sponsoring Committee:</i>	<i>OPTN Data Advisory Committee</i>
<i>Public Comment Period:</i>	<i>August 2, 2019 – October 2, 2019</i>

## Executive Summary

The National Organ Transplant Act of 1984 requires that the Organ Procurement Transplantation Network (OPTN) “collect, analyze, and publish data concerning organ donation and transplants.”<sup>1</sup> *Policy 18: Data Submission Requirements* establishes the OPTN’s data requirements. OPTN members are required to complete and submit data on transplant candidates, recipients, and donors. The data are submitted electronically through UNet<sup>SM</sup>, a secure web-based data collection system, with the exception of certain data associated with Vascularized Composite Allografts (VCA). **Appendix A** provides a glossary of terms and meanings.

In order to collect the highest quality data, this proposal addresses some of the identified gaps in current policy and practice. For example, the OPTN Data Advisory Committee (hereafter, “Committee”) proposes clarifying when data elements collected using the Transplant Information Electronic Data Interchange® (TIEDI) are required to be submitted (**Table 1**).<sup>2</sup> (See **Appendix B** for more detail regarding the TIEDI data reporting requirements.) The Committee also proposes limiting members’ ability to change data submitted through TIEDI. Finally, the proposal revises certain policy language to make it more consistent with members’ data entry experiences.

**Table 1: Titles and Acronyms of TIEDI Data Collection Instruments and Responsible OPTN Member**

Title	Acronym	Responsible Member
Deceased Donor Registration	DDR	Organ Procurement Organization
Donor Histocompatibility	DHS	Histocompatibility Lab
Living Donor Follow-up	LDF	Transplant Program
Living Donor Registration	LDR	Transplant Program
Recipient Histocompatibility	RHS	Histocompatibility Lab
Transplant Candidate Registration	TCR	Transplant Program
Transplant Recipient Follow-up	TRF	Transplant Program
Transplant Recipient Registration	TRR	Transplant Program

Source: OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

<sup>1</sup> NOTA, 42 U.S.C. § 273 et. seq. and OPTN Briefing Paper, “Proposed Modifications to Data Elements on the following TIEDI forms: TCR, TRR, TRF, LDR, LDF, DDR, HF – BP,” Policy Oversight Committee, November 11, 2011, <https://bodandcommittees.unos.org/archive/Documents/Proposed%20Modifications%20to%20Data%20Elements%20on%20the%20following%20Tiedi%20forms-%20TCR%2C%20TRR%2C%20TRF%2C%20LDR%2C%20LDF%2C%20DDR%2C%20HF%20-BP.pdf>.

<sup>2</sup> As used here, the TIEDI data collection instruments represent the section of UNet<sup>SM</sup> where data coordinators and program staff members receive, complete, and submit data on transplant candidates, recipients, and donors to the OPTN. See, OPTN Briefing Paper, “Proposed Modifications to Data Elements on the following TIEDI forms: TCR, TRR, TRF, LDR, LDF, DDR, HF – BP,” Policy Oversight Committee, November 11, 2011.

The proposal will promote the efficient management of the OPTN in several ways. It clarifies the need for submitting accurate, high-quality data at the time of entry. It seeks to achieve this by improving the timelines for submitting data, and limiting the ability to change data after final submission. These actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement, and for the OPTN's evaluation of transplant system performance. In addition, researchers, such as the Scientific Registry of Transplant Recipients (SRTR), who also study and assess transplant system performance, will benefit from the proposed efforts to improve data quality. It also aligns with the Final Rule's requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs.<sup>3</sup>

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<sup>3</sup> "Organ Procurement and Transplantation Network." Federal Register 63:63 (April 2, 1998) p. 16320.

## Problems the Proposal Will Address

Current policies and practices evolved from a time when members submitted data to the OPTN using paper forms. UNOS staff would then manually enter the data on the members' behalf. Following data entry, UNOS staff would request that the members review the accuracy of the entered information.

In the years since, technological changes have resulted in members submitting their data electronically and conducting their own data quality checks. The expectation has been that OPTN members will submit accurate, high-quality data upon entry. In 2014, the OPTN Board of Directors highlighted the importance of data accuracy by approving policy language that explicitly stated that data must be accurate when submitted.<sup>4</sup> Members are expected to perform quality checks prior to data entry. This concept of data quality assurance has led some members to question whether the submission timeframes should be extended.

OPTN members and other data users have since raised concerns about the integrity of the submitted data. They point to the lack of a singular requirement for timely data submission as a problem. They also point out the ability of members to change data indefinitely after submission and the high volume of changed data as reasons to question the data's accuracy.

## Members Report Data Submission Requirements Are Unclear

During the course of the project, member institutions provided feedback that the deadlines for data submission are confusing. For example, *Policy 18.1: Data Submission Requirements* and *Policy 18.4: Data Submission Standards* provide different requirements for when data are to be submitted. *Policy 18.1* identifies specific timeframes for data submission based on when other events occur. For example, information associated with the Recipient Histocompatibility collection instrument is required within 30 days of the transplant hospital removing the candidate from the waiting because of transplant.<sup>5</sup> However, *Policy 18.4* mandates that members must submit 95 percent of their required forms within three months of the form due date, and 100 percent of the forms within six months of the form due date.<sup>6</sup> That it is permissible for a certain percentage of reported data to be late directly conflicts with *Policy 18.1's* requirement that all data must be submitted by the deadlines.

The issue was made more confusing for transplants hospitals when the Centers for Medicare and Medicaid Services (CMS) adopted language similar to *Policy 18.4* in its Conditions of Participation (CoP) among transplant hospitals.<sup>7</sup> Under CMS' CoPs, members have 90 days after the OPTN's established due date to submit at least 95 percent of their data.

The unclear policies increase the burden of both members trying to understand the data submission requirements and UNOS staff responding to members' requests and questions. Additionally, the Final Rule emphasizes the importance of collecting institution-specific performance data to evaluate the quality of transplantation programs.<sup>8</sup> It is important for the collected data to accurately reflect

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<sup>4</sup> OPTN, "Important Policy Notice: Changes to OPTN Bylaws and Policies form actions at November Board of Directors Meeting," December 12, 2014, p. 54.

<sup>5</sup> OPTN *Policy 18.1: Data Submission Requirements*.

<sup>6</sup> OPTN *Policy 18.4: Data Submission Standards*.

<sup>7</sup> 42 C.F.R. §482.80 and 42 C.F.R. §482.82, 2007.

<sup>8</sup> "Organ Procurement and Transplantation Network." Federal Register 63:63 (April 2, 1998) p. 16320.

transplant information because of its use in organ allocation, policy development and compliance, and patient safety.<sup>9</sup>

## Data Changes Following Submission Raise Accuracy Concerns

Members' ability to submit data and then make changes has raised data integrity concerns. Presumably, members perform quality assurance checks on their data when providing them to the OPTN. Because members are able to change data following their quality assurance process and after submission, using the data can affect analysis of allocation policy and practices, policy analysis, and other uses of the information. For example, SRTR uses TIEDI data to produce risk adjusted models for use with the Program Specific Reports (PSR). The models are based on the data available at a point-in-time. SRTR has found that members make so many data changes following the creation of the models that their validity is negatively impacted.

Situations like what SRTR experienced lead to a lack of trust in both the accuracy and completeness of the OPTN data. As previously mentioned, *Policy 18.1* states that members must enter accurate data according to the established timeframes. As such, it appears the policy's intent was to make members verify the accuracy of their data prior to submission, not to permit multiple changes to data that were already considered 'final' from an accuracy standpoint.

## Why Should You Support This Proposal?

The changes proposed by the Committee will result in improved data quality. High data quality are critical when it comes to measuring program performance and informing the public about patient outcomes. This is reflected in both the Final Rule and the OPTN's Principles of Data Collection. Improving data integrity will in turn produce better decision-making. Conversely, questions about data integrity can erode the public's trust in the research findings based on the data. In addition, such issues can lead OPTN members to question the ability of the OPTN to identify and correct the problem.

The proposed policy improves data integrity by establishing one set of data submission deadlines and by providing members with additional time to perform data quality assurance activities of their data prior to submission. By eliminating *Policy 18.4*, the proposal clearly states that member data is due to the OPTN by the dates established in *Policy 18.1*.

The proposal also addresses how OPTN members will make changes to their already submitted data. Members are now able to change submitted data under any circumstances. While this was intended to help members ensure their submitted data were correct, the lack of a formal data correction process has led to some instances where large volumes of changes are made well after the data have been submitted as final.

The proposal establishes a process that will slightly increase the burden on members to make such data changes. The change is intended, in part, to make members consider improving their data reporting and quality assurance efforts so that data are correct at the due date, and there is less reason for post-submission changes. By increasing the number of actions members must complete to change data, the proposal also seeks to restore the public's trust in the accuracy and completeness of the OPTN data. Furthermore, by requiring a leadership position at each member institution to review and approve all

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<sup>9</sup> OPTN, "Principles for Data Collection," Board approved language, December 13, 2006.

changes it should improve institutional awareness of issues. Greater transparency into their data-related processes should also help members identify and correct the root causes leading to their need to change data. Additionally, the proposed process should improve transparency by identifying and reviewing the reasons why members change submitted data, who is approving such changes, and how frequently changes are occurring.

Because the proposed changes may pose challenges for some members, the Committee has also identified several types of assistance to help members implement the recommended changes. These include extending the amount of time members have to submit data collected on the TIEDI instruments, refining existing tools available in the UNet Data Services portal to help members identify issues prior to submission, and creating new Data Services portal tools to provide members with a comparison of their own data quality versus aggregated data quality measures of all members.

## Background

The Committee agreed to a scope of work which included addressing two primary objectives: the lack of singular requirements for timely data submission and members' ability to make post-submission changes to data.

The Committee is comprised of transplant hospital representatives, OPO representatives, researchers, and data coordinators. Committee members were selected, in part, based on their experience with data collection, quality control, and analysis. When evaluating the information and issues associated with this project, Committee members relied on their experiential expertise. The members also relied on each other's understanding of the differences in practices, as well as the types of challenges different member institutions experience.

The Committee collaborated with multiple other OPTN committees in developing this proposal. The Committee sought feedback about why members often do not submit data within the existing timeframes. The Committee also sought feedback regarding the circumstances by which data may need to be amended after it is formally submitted.

UNOS staff presented background information about the project and the proposed solutions to the following OPTN committees:<sup>10</sup>

- Histocompatibility
- Living Donor
- OPO
- Transplant Administrators
- Transplant Coordinators
- Vascularized Composite Allograft

The presentation and discussion focused on members' data submission compliance rates and data changes. The committee's provided feedback about the potential impact of eliminating Policy 18.4 and using only the data submission timeframes found in *Policy 18.1*. Committee members were also asked to

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<sup>10</sup> Dates of presentations made to other OPTN committees: Histocompatibility, March 26, 2019; Living Donor, April 1, 2019; Vascularized Composite Allograft, April 12, 2019; OPO, April 16, 2019; Transplant Administrators, April 24, 2019; Transplant Coordinators, April 25, 2019.

consider the impact of preventing members from changing data after officially submitting it to the OPTN. In addition to presenting to the aforementioned OPTN committees, the Data Advisory Committee Chair also discussed the project and proposed solutions with the chairs the Histocompatibility, Pancreas, and Pediatrics Committees.<sup>11</sup>

The majority of the committees who received the presentation agreed with the concept of removing *Policy 18.4*. While several of the committees indicated general support for the idea of preventing data changes following submission, they reserved judgement until more details about how such a “lock” would be designed.

The Committee relied on multiple sources of information in developing the proposal. They considered analyses and findings reported by UNOS Research staff addressing submission compliance rates and changes to submitted data. Committee members heard from other OPTN committees whose memberships will be impacted by the changes. The Committee also considered SRTR’s findings regarding the data integrity impact associated with member data changes around the Program Specific Reports. The proposed solutions address the identified data integrity concerns.

## Proposed Solutions

The Committee proposes addressing the data quality concerns by modifying the initial submission deadlines associated with the TIEDI data and reducing members’ ability to make changes following submission. Together, the resulting changes will improve all uses of the OPTN data, such as research analyses and program specific reports.

### Clarify When Data Are Due by Extending Timeframes in Policy 18.1 and Eliminating Policy 18.4

The Committee chose first to address the issues associated with the data submission timeframes. Committee members indicated that this had at least two benefits. First, it would likely be more straightforward than their deliberations about preventing data changes. Second, it would improve their understanding of the existing process.

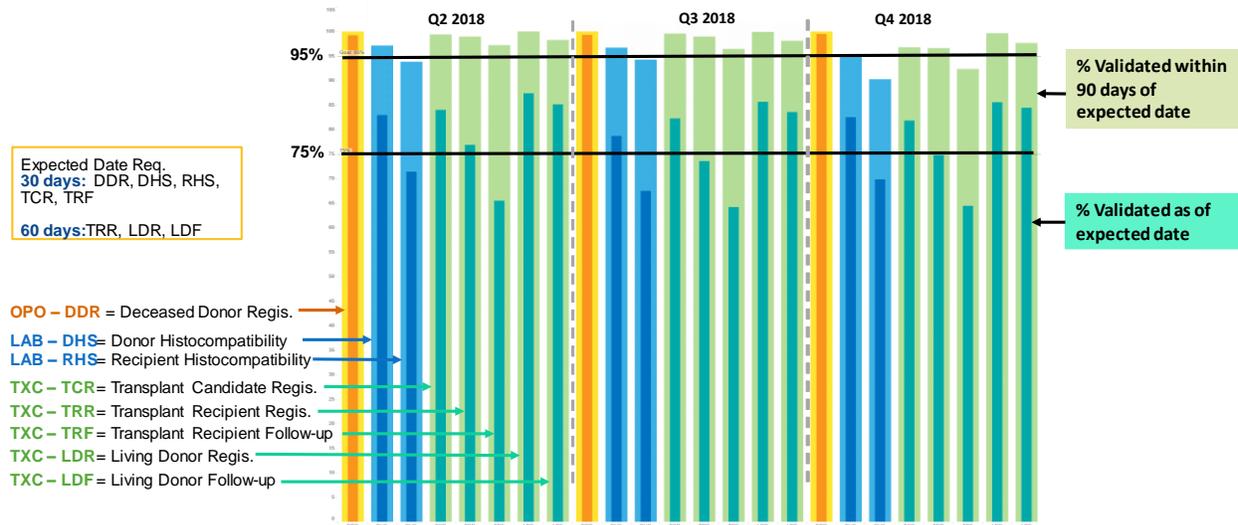
The Committee reviewed submission rates by data collection instrument and by member type to better understand member performance and behavior. **Figure 1** shows the percentage of TIEDI data collection instruments that were submitted by the timeframe established in Table 18-1 during the second, third, and fourth quarters of 2018.<sup>12</sup> The figure also shows the number of instruments submitted within 90 days of the Table 18-1 timeframes. As the figure shows, histocompatibility labs submitted approximately 70 to 85 percent of the Donor Histocompatibility and Recipient Histocompatibility data collection instruments within the 30 day due date. For the most part, labs submitted about 95 percent of the forms within 90 days following the due date. Likewise, transplant center submission rates were between 65 and 85 percent by the due date, and typically higher than 95 percent within 90 days of the due date. Committee members expressed concerns about the low initial submission rates for the transplant programs and histocompatibility laboratories.

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<sup>11</sup> Discussions with and emails provided by the Data Advisory Committee chair, June 10, 2019.

<sup>12</sup> <https://tableauprod.unos.org/#/views/ResearchMetricsDashboard/FormsSubmissionRates?iid=1>, as of January 30, 2019.

**Figure 1: Percentage of Certain Forms Submitted by Due Date Was Concerning, but Most Forms Were Submitted Within Days Following Due Date**



Source: UNOS, Tableau: Form submission Rates, <https://tableauprod.unos.org/#/views/ResearchMetricsDashboard/FormSubmissionRates?.iid=3>.

UNOS staff asked other OPTN committee members to describe the factors impacting their ability to meet the submission timelines found in *Policy 18.1*. The respondents identified the difficulty associated with obtaining certain data elements. Others reported that because data entry and validation are still largely manual processes, they require large amounts of time to complete. For instance, members of the Histocompatibility Committee expressed concerns that a large amount of staff time is needed to complete the Donor Histocompatibility and Recipient Histocompatibility collection instruments. Members also pointed to instances where re-typing of individuals has occurred resulting in data changes needed well after the 30 day deadline for both collection instruments.

While data submission compliance rates suggest that members do not consistently meet the due dates established in *Policy 18.1*, the compliance rates do indicate members are generally able to submit data within 90 days following the due date. The Committee considered the difference during its discussion of the timeframes in *Policy 18.1*. The Committee members acknowledged that member institutions would be required to spend more time and resources ensuring their data entry activities are completed in enough time to then permit adequate data validation to occur. To help member institutions complete data entry and validation activities by the due dates, the Committee recommended extending the due dates in *Policy 18.1* for the TIEDI data collections instruments.

In addition to the submission compliance rates, the Committee also considered the findings of an analysis performed by UNOS Research staff showing the number of days from the due date to the last modification made to the collection instrument. Analyzing the TIEDI data collection instruments expected during 2017, Research staff reported that members continued changing data on most TIEDI data collection instruments after the due date (**Table 2**). For example, as **Table 2** shows, 42 percent of the DDRs submitted in 2017 had at least one data element changed following the due date. The percentage of TIEDI collection instruments where the last modification occurred on or before the due date ranged from a high of 82 percent for the Donor Histocompatibility collection instrument and a low of 33 percent for the Transplant Candidate Registration collection instrument.

**Table 2: Percent of TIEDI Data Collection Instruments Changed Following the Due Date**

TIEDI Instrument	Due Date	Number of Forms	Before or on due date	Within 30 days	31-60 days	61-90 days	More Than 90 days
DDR	30 days after feedback completed	10,334	59%	17%	7%	5%	13%
DHS	30 days after DDR validated	16,402	82%	14%	2%	1%	1%
RHS	30 days after waitlist removal	31,246	73%	20%	3%	1%	3%
LDR	60 days after living donor feedback	6,084	76%	12%	2%	1%	9%
TCR	30 days after registering on waitlist	59,051	33%	9%	5%	5%	49%
TRR	60 days after waitlist removal	34,743	56%	13%	4%	4%	24%
LDF	60 days after anniversary date	17,870	79%	14%	3%	1%	3%
TRF	30 days after anniversary date	342,516	66%	19%	7%	6%	2%

Note: Percentages may not sum to 100% due to rounding.

Source: UNOS staff analysis of submitted TIEDI data, May 1, 2019.

Based on the findings, the Committee decided to extend the due dates associated with the TIEDI data collection instruments. **Table 3** identifies the instrument, the triggering event, the current timeframe, the proposed timeframe, and the change in the number of days.

**Table 3: Current and Proposed Due Dates for TIEDI Data Collection Instruments**  
(Based on days after triggering event)

TIEDI Collection Instrument	Triggering Event	Current	Proposed	Change
DDR	Feedback completed	30	60	+30
DHS	DDR validated	30	60	+30
RHS	Waitlist removal	30	60	+30
LDR	Living donor feedback	60	90	+30
TCR	Registration on waitlist	30	90	+60
TRR	Waitlist removal	60	90	+30
LDF	Anniversary date	60	90	+30
TRF	Anniversary date	30	90	+60

Source: OPTN Data Advisory Committee, Meeting minutes from May 1, 2019.

## Improve Data Quality by Implementing Data Change Process and Reporting Requirements

Committee members began discussing the implications of members making changes to data after the data were submitted and reports had been produced as early as April 2018.<sup>13</sup> The members agreed that this was a problem and discussed possible ways to remedy the issue. The Committee discussed the possibility of locking the data in the system after it had been submitted so that changes could not be made. Concerns that there may be valid reasons for revising data after submission led the Committee

<sup>13</sup> OPTN Data Advisory Committee, Meeting Minutes, April 4, 2018.

members to consider a process for when the data could be unlocked and a way to determine the circumstances under which unlocking the data would be permissible.

As part of its deliberations, the Committee received a presentation from SRTR staff describing one of the data integrity problems it had encountered after releasing the new kidney program specific report (PSR) model. In December 2015, SRTR performed a detailed analysis of OPTN members’ data changes around the time the new kidney Program Specific Reports (PSR) models were released during October 2014. Based on their findings, SRTR reported concerns that the data changes SRTR found were making members’ patients medical status appear riskier than the patients actually were. SRTR staff compared the data elements used for the deceased donor graft survival and living donor graft survival models to determine which data elements were changed after programs became aware of the new models.<sup>14</sup> According to SRTR staff, the analysis found examples of more than 3,500 records where at least one variable had been changed related to the deceased donor kidney model (**Table 4**).

**Table 4. Changes to Deceased and Living Donor Adult Graft Survival Kidney Model Variables**

Description of Change	Deceased	Donors	Living	Donors
	Number	Percent	Number	Percent
Candidate total serum albumin	1,099	4%	411	3%
Recipient pre-transplant blood transfusions	816	3%	365	3%
Recipient Body Mass Index (BMI)	607	2%	275	2%
Candidate Peripheral Vascular Disease (PVD)	565	2%	188	1%
Recipient primary insurance	268	1%	103	1%
Candidate Chronic Obstructive Pulmonary Disease (COPD)	254	1%	115	1%
Recipient primary diagnoses at transplant	243	1%	109	1%
Recipient cold ischemia time	772	3%	NA	NA
Donor clinical infection	399	1%	NA	NA
Candidate previous malignancy	194	1%	NA	NA
Donor Body Mass Index (BMI)	NA	NA	202	1%
Epstein-Barr Virus (EBV) (Donor/Recipient)	NA	NA	193	1%
Recipient medical condition at transplant	NA	NA	145	1%
<b>Total Number of Changed Records</b>	<b>3,542</b>	<b>NA</b>	<b>1,338</b>	<b>NA</b>

Source: SRTR staff presentation to OPTN Data Advisory Committee, Meeting minutes from April 29, 2019.

SRTR provided transplant programs with a 30 day preview of the new risk adjustment models. The preview was intended to provide transplant programs with the opportunity to review the data elements incorporated in the new risk adjustment models. Because transplant programs are permitted to edit data after it has been reported to the OPTN, some programs took the opportunity to revise existing data values as well as enter data that had been previously missing.

Such changes to data already considered final affects the stability of the entire OPTN dataset. As SRTR described at the time, accurate data are not only critical to the development of the PSRs, but are also critical to the development of policy and research. At the time, SRTR staff suggested that the OPTN consider closing data entry after a specified time period, auditing the reported data, and removing unnecessary data elements.

<sup>14</sup> Scientific Registry of Transplant Recipients (SRTR), “OPTN/SRTR Data Quality “presentation made to the OPTN Data Advisory Committee on April ,29, 2019, slides seven.

The Committee considered several alternative approaches to restricting or preventing data changes following submission. The processes discussed by the Committee included:

- Prospective review and approval by the OPTN before members could change previously submitted data
- Prospective review and approval by the Committee or a sub-committee before members could change previously submitted data
- Permit changes to previously submitted data by requiring an explanation of why the change is necessary, as well as official approval for the change from a designated administrator at the member

**Appendix C** contains the advantages and disadvantages the Committee identified for each alternative.

After substantial discussions about preventing or at least limiting data changes, the Committee opted for an approach that strikes a balance between the need to maintain accurate and stable data for policy development and performance measurement, and the need to allow members to correct known data errors. Under the process, which only applies to data values collected using the TIEDI data collection instruments, members will need to complete more steps than they currently do to make data changes as part of *Policy 18.1*. A member who identifies an error will be able to ‘unlock’ their data in order to make a correction. However, the member will no longer be able to simply change the data values. Instead, the Committee proposes requiring members to submit an explanation detailing why the data values are being changed. In addition, members are required to submit the name of an individual at their institution who has reviewed the proposed change and provided approval to make the change.

Requiring an approver is intended to help members develop institutional knowledge of why their data are being changed. This knowledge should also help members identify systematic issues with their data entry and validation practices. By identifying their data challenges, members can better target their responses by providing additional data training or revises broken practices, for example.

The Committee received feedback from SRTR staff and its own members about the problems associated with implementing a strict data lock. For example, SRTR staff pointed out that data integrity is a primary principle of the project. Restricting changes to only rare or unusual circumstances would prevent members from correcting the single, data keying related errors that members claim are the largest cause of problems. As such errors accumulated in the OPTN dataset, so too would the questions about data accuracy and integrity.

The Committee also considered how preventing data changes might impact members and data integrity in cases when data are not available when the data collection instrument is due or new values are reported following the due date. This can be particularly true for the follow-up collection instruments, such as the Transplant Recipient Follow-up (TRF) tool. Currently, transplant hospitals are required to submit the information collected using the TRF within 30 days after the six-month and annual anniversary of the transplant date until the recipient’s death or graft failure, or within 14 days from notification of the recipient’s death or graft failure. Therefore, after learning of a recipient’s death, the program has 14 days to update the TRF data fields and submit them to UNet. No data changes would be permitted following submission or after the due date. However, the Committee was told that in some cases, transplant programs may not receive final autopsy reports until six months following the recipient’s death. The Committee was also told that the final autopsy report may have corrected data values, or may have values that were initially submitted as missing. If the data lock were implemented as proposed, the transplant program would not be able to make any data changes to the TRF to reflect the more accurate information found on the autopsy report.

The screenshot in **Figure 2** is an example of what members may encounter when trying to change data in the system if the Committee’s proposal is implemented.

**Figure 2: Potential Way Members Will Have to Report a Reason for Changing Data and the Name of the Individual at the Member Institution Who Approved the Change**

Source: UNOS staff conceptualization.

## Providing Members With Additional Resources to Improve Data Quality

To assist members with integrating the new data submission requirements into their existing practices, UNOS Research staff identified ways existing data tools could be improved, as well as new resources that could be added.<sup>15</sup> For instance, transplant programs and OPOs currently access monthly “Data Validation” reports through the Data Services portal in UNet. Research staff propose increasing the frequency to weekly reporting. The change would allow transplant programs, OPOs, and histocompatibility labs to easily identify and review any data elements with missing, unknown, or suspect values, in real time. These tools should help members quickly identify potential data discrepancies well before the submission deadlines. In addition, the reports will be expanded to cover all data elements on the TIEDI collection instruments.

Research staff also propose creating a new data quality dashboard to allow members to visually review their data quality in aggregate form. This will help members identify more global inconsistencies in reporting based on comparisons with national data. The dashboard is intended for use by the members’ data quality manager, transplant administrator, or similar role with broad data quality oversight. Currently, members can only perform such a review data collection instrument by instrument. The change allows members to more easily identify systematic issues with their submitted data. For example, members will be able to see a comparison of their missing, unknown, or suspect values per data element and data collection instrument. They will also be able to see how their submitted data compare to all other submitted data. The dashboard also allows them to identify how often data elements are modified following official submission along with the reason(s) for the modification(s).

<sup>15</sup> Descriptions provided by UNOS Research staff, email, May 30, 2019.

## Implementation

The proposal most immediately impacts the OPTN members. The proposed changes clarify existing submission requirements and extend the due dates for data submitted using a TIEDI data collection instrument. The clarification and additional time should allow members to complete their data entry and data validation activities within the timeframes required for submission. Additionally, OPTN members will now be required to explain why data values are being changed following their official submission prior to making such changes. Members will also need to identify the individual responsible for approving the data changes as part of the process. Eventually, all transplant candidates, recipients, donors, and their families may be impacted as data quality improves and can be better used in all facets of transplantation.

### How Will the OPTN Implement This Proposal?

Programming changes are required and reflect the primary hours associated with this proposal. For example, the entire process for unlocking data collection instruments, capturing members' data change reasons, and approver information will need to be programmed and tested.

### How Will Members Implement This Proposal?

The proposed changes will require all members to review their existing data entry and validation work flows. Leadership at each member institution should be involved with the reviews. Not only will this raise general awareness, but it would also present an opportunity to quickly address any identified process, training, and performance issues. The level of knowledge regarding the type, frequency, and reasons for data changes likely varies by institution. A deeper understanding, could help members suggest ways to improve the quality of the data being submitted.

Changes to processes, training, and staffing levels identified through the reviews could result in potential cost increases at the member institutions. Additionally, the current policies allow for some leeway with timeliness of data entry and members are accustomed to the current reporting timelines. As a result, changing member submission practices will likely require substantial outreach.

#### Transplant Hospitals

Transplant hospitals are responsible for submitting data for five of the eight TIEDI collection instruments discussed in this proposal. The proposed changes will likely require transplant hospitals to comprehensively review their existing practices associated with data collection, data entry, and data validation. Leadership at some institutions may be unaware of their current processes and any associated issues. Because of the significance of the proposed changes, even institutions with strong practices will want to perform a comprehensive review to identify areas of potential improvement.

#### OPOs

OPOs will need to review existing data entry and validation practices to ensure they can comply with the data submission changes. As previously described, some members of the OPO committee reported that 30 days is not enough time for their institutions to adequately review data entered on the DDR before it is submitted under the current process. The Committee considered the OPO members' comments in addition to the analyses provided by UNOS Research staff when deciding to extend the DDR submission timeframe from 30 days to 60 days under the proposal. Nonetheless, OPOs without adequate data

quality processes will need to consider how they will improve existing practices as well as the resource levels needed to achieve and maintain the appropriate rigor.

### **Histocompatibility Laboratories**

Histocompatibility laboratories are responsible for submitting data for the Donor Histocompatibility and Recipient Histocompatibility collection instruments. Members of the Histocompatibility Committee expressed concern that large amounts of staff time are needed to complete the collection instruments. While the proposal extends the due dates from 30 to 60 days following each triggering event, the labs should take the opportunity to comprehensively review their existing practices associated with data collection, data entry, and data validation. Leadership at some institutions may be unaware of their current processes and any associated issues. Because of the significance of the proposed changes, even institutions with strong practices will want to perform an intense review to identify areas of potential improvement.

## **Will This Proposal Require Members to Submit Additional Data?**

Implementation of the proposed changes requires additional data reporting by members. Specifically, members attempting to change previously submitted data are required to provide an explanation of why the changes are necessary. Initially, members will have a limited set of reasons from which to choose, in addition to being able to provide a more specific explanation through an open text field. In addition to the explanation, members will also need to identify an individual at their institution who was responsible for approving the data change.

In December 2006, the OPTN Board of Directors approved the OPTN Principles of Data Collection.<sup>16</sup> The Board also required that all new data elements added to the OPTN data collection systems meet the principles. The data elements proposed for collection meet several of the stated principles and allow the OPTN to:

- Develop transplant, donation, and allocation policies;
- Determine if institutional members are complying with policy;
- Determine member-specific performance; and
- Fulfill the requirements of the OPTN Final Rule.

In addition, the proposal meets the requirement that all new data collection activities be subject to public comment.

This proposal is subject to the Paperwork Reduction Act of 1995 guidelines for collecting additional information and may require an additional public comment posted in the Federal Register sponsored by the Health Resources and Services Administration (HRSA). This may impact the implementation timeline.

## **How Will Members Be Evaluated for Compliance With This Proposal?**

The proposed language will not change the current routine monitoring of OPTN members. All policy requirements and data entered in UNet<sup>SM</sup> may be subject to OPTN review, and members are required to provide source documentation as requested.

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<sup>16</sup> OPTN Board of Directors, Meeting Minutes, December 13-14, 2006, pp. 35-6.

OPTN staff will continue to review rates of compliance with submission dates, as specified in Policy 18.1.B *Timely Submission of Certain Data*, for the following data collection instruments:

- Deceased Donor Registration (DDR)
- Donor Organ Disposition
- Potential Transplant Recipient (PTR)
- Living Donor Registration (LDR)

For OPOs, OPTN staff will also continue to review a sample of deceased donor records to verify that data reported on the DDR are consistent with source documentation. For living donor recovery hospitals, the OPTN Contractor staff will continue to review a sample of living donor medical records to verify that data reported on the LDR are consistent with source documentation.

## **How Will the Sponsoring Committee Evaluate Whether This Proposal Was Successful Post Implementation?**

The proposed policy language requires the Committee to report at least annually to the Board of Directors the following:

- Data submission compliance rates
- Frequencies of data changes following submission, as well as the reported reasons associated with the changes; and
- Other relevant information identified by the Committee.

To assist in the Committee's reporting, UNOS Research staff and IT staff will provide regular reporting updates to the Committee.

## **Summary**

Implementing a single policy addressing data submission requirements and deadlines addresses when data are due, and underscores the expectation that submitted data should be accurate. Implementing a multi-step process requiring members to "unlock" their submitted data and provide explanation for the changes prior to re-submission will improve data quality in several ways. First, members will likely seek to submit accurate data initially to avoid the steps required to make changes. Second, members' actions will be under greater scrutiny when they must explain why submitted data are being changed as well as provide the name of an individual who approved the change. Third, because of the proposed data collection and reporting associated with the process, it benefits members to review their data entry and validation practices to identify and implement potential improvements, so as to avoid reporting to the Committee and/or Board of Directors. Members are also being provided additional tools and resources to help them meet the proposed requirements. By collecting the reasons members change their data will also help with future policy development, as the Committee will be able to consider the appropriateness of the explanations provided.

These actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement. High-quality data will also improve the OPTN's policy development activities and evaluation of transplant system performance. Additionally, other researchers who study and assess transplant system performance will benefit from data quality improvements. It also aligns with the Final Rule's requirement that timely and institution-specific

performance data be made publicly available in order to appraise the quality of transplantation programs

The Committee encourages all interested individuals to comment on the proposal in its entirety. Members are also asked to comment on both the immediate and long-term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board of Directors in considering the proposal and its impact on the community.

The Committee also requests public comment addressing the following questions:

1. What are the most common reasons your organization changes TIEDI-specific data after submission?
2. What are the most common factors preventing your organization from submitting accurate data within the established timeframes?
3. What tools would help your organization (a) submit data on time, and (b) quickly identify data discrepancies?

1 **Policy Language**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

2 **18.1 Data Submission Requirements**

3 **18.1.A Accurate Submission of Data**

4 ~~OPTN m~~Members must ~~report~~ submit accurate data to the OPTN Contractor according to ~~Table 18-1~~  
 5 ~~below~~. Members are ~~responsible for providing~~ must maintain documentation ~~upon request to verify~~  
 6 demonstrating the accuracy of all data ~~that is submitted to the OPTN through the use of standardized~~  
 7 ~~forms~~.

8  
 9 **18.1.B Timely Submission of Certain Data**

10 Members must submit data to the OPTN Contractor according to Table 18-1.

11  
 12 **Table 18-1: Data Submission Requirements**

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor Histocompatibility (DHS)</i>	<del>3060</del> days after the OPO <del>submits the deceased donor registration</del> <u>DHS record is generated</u>	Each <del>heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory</del> <u>living and deceased donor</u>
Histocompatibility Laboratory	<i>Recipient Histocompatibility (RHS)</i>	<del>Either of the following:</del> <ul style="list-style-type: none"> <li><del>3060</del> days after the transplant hospital removes the candidate from the waiting list because of transplant</li> <li><del>30</del> days after the transplant hospital <u>submits the recipient feedback</u></li> </ul>	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, <del>all</del>	<del>Death Notification records</del> <u>Registration (DNR)</u>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, <del>all</del>	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor	All deaths reported by a hospital to the OPO

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
		hospital reports a death to the OPO	
Allocating OPO	<i>Potential Transplant Recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	<i>Donor Organ Disposition (Feedback)</i>	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	<i>Deceased Donor Registration (DDR)</i>	<del>30</del> 60 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living Donor Feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital  This does not apply to VCA donor organs
Recovery Hospitals	<i>Living Donor Feedback</i>  Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Living Donor Adverse Events</i>	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	<i>Living Donor Registration (LDR)</i>	<del>60</del> 90 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs
Recovery Hospitals	<i>Living Donor Follow-up (LDF)</i>	<del>60</del> 90 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
			This does not apply to VCA, domino donor, and non-domino therapeutic donor organs
Transplant hospitals	<i>Organ Specific Transplant Recipient Follow-up (TRF)</i>	<p><i>Either of the following:</i></p> <ul style="list-style-type: none"> <li>• <del>30</del>90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure</li> <li>• 14 days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital
Transplant hospitals	<i>Organ Specific Transplant Recipient Registration (TRR)</i>	<del>60</del> 90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital <del>submits the recipient feedback form</del> removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	<del>Recipient feedback</del> <i>Waiting List Removal for Transplant</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient Malignancy (PTM)</i>	30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	<i>Transplant Candidate Registration (TCR)</i>	<del>30</del> 90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

14 **18.1.C** **Changes to Submitted Data**

15 Upon expiration of the corresponding timeframe listed in Table 18-1, data submitted using the following  
 16 instruments are considered final:

- 17
- 18 • Deceased Donor Registration (DDR)
- 19 • Donor Histocompatibility (DHS)
- 20 • Recipient Histocompatibility (RHS)
- 21 • Transplant Candidate Recipient (TCR)
- 22 • Transplant Recipient Registration (TRR)
- 23 • Living Donor Registration (LDR)
- 24 • Transplant Recipient Follow-up (TRF)
- 25 • Living Donor Follow-up (LDF)

26

27 Changes to final data will not be permitted unless the member reports, within the data collection system  
 28 prior to making the changes, both the approval of the member’s official OPTN Representative (or  
 29 designee) and the reason for the changes.

30

31 **18.1.D** **Reporting**

32

33 The Data Advisory Committee must report to the Board of Directors at least annually all of the following:

- 34 • Data submission compliance rates;
- 35 • The frequencies of data change following submission and reasons reported; and
- 36 • Other relevant information identified by the Committee.

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39 **18.2 Timely Collection of Data**

40 Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living  
 41 donors is based on recipient or living donor status at a time as close as possible to the specified transplant event  
 42 anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from  
 43 the patient.

44 **Table 18-2: Timely Data Collection**

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first.  This does not apply to VCA transplants.
Recovery hospital	<i>Living donor follow-up (LDF)</i>	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date.

Information is timely if this Member:	Collects this information for this form:	Within this time period:
		This does not apply to VCA transplants.

46

47 **18.3 Recording and Reporting the Outcomes of Organ Offers**

48 The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the  
 49 outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN  
 50 Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report  
 51 this information. The OPO or the OPTN Contractor must obtain PTR refusal codes directly from the physician,  
 52 surgeon, or their designee involved with the potential recipient and not from other personnel.

53

54 If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate  
 55 the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report  
 56 different refusal codes, then the OPTN Contractor will use the transplant hospital’s refusal code for data analysis  
 57 purposes.

58

59 If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

60

61 This policy does not apply to VCA organ offers; instead, members must document VCA offers according to *Policy*  
 62 *18.1: Data Submission Requirements*.

63

64 **18.4 Data Submission Standard**

65 **18.4.A Timely Data Submission**

66 *Table 18-3* below sets standards for Members’ data submission.

67

68

**Table 18-3: Data Submission Standard**

The following members:	Must submit:	Of their:	Within:
OPOs, transplant hospitals and Histocompatibility Laboratories	95%	Required forms	Three months of the form due date
OPOs, transplant hospitals and Histocompatibility Laboratories	100%	Required forms	Six months of the form due date
OPOs	100%	PTR refusal code forms	30 days of the match run date
OPOs and transplant hospitals	100%	Donor and recipient feedback forms	30 days of the transplant date

69

70 If a member fails to submit forms by the standards above, then the OPTN Contractor will attempt to assist  
 71 the member. However, if this is unsuccessful, the Membership and Professional Standards Committee  
 72 (MPSC) may review the members’ actions. If the MPSC determines that the member continues to be non-  
 73 compliant with data submission requirements, then the MPSC may recommend an onsite audit to retrieve  
 74 the missing data at the members’ expense.

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## 18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

### 18.5.A Reporting Requirements after Living Kidney Donation

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes *all* of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
6. Maintenance dialysis
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Required kidney laboratory data includes *all* of the following:

1. Serum creatinine
2. Urine protein

### 18.5.B Reporting Requirements after Living Liver Donation

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
  - 75% of their living liver donors on the 6 month LDF

- 123 • 70% of their living liver donors on the one year LDF

124

125 Required liver donor status and clinical information includes *all* of the following:

- 126 1. Patient status
- 127 2. Cause of death, if applicable and known
- 128 3. Working for income, and if not working, reason for not working
- 129 4. Loss of medical (health, life) insurance due to donation
- 130 5. Hospital readmission since last LDR or LDF was submitted
- 131 6. Liver complications, including the specific complications
  - 132 • Abscess
  - 133 • Bile leak
  - 134 • Hepatic resection
  - 135 • Incisional hernias due to donation surgery
  - 136 • Liver failure
  - 137 • Registered on the liver candidate waiting list

138 Required liver laboratory data includes *all* of the following:

139

- 140 1. Alanine aminotransferase
- 141 2. Alkaline phosphatase
- 142 3. Platelet count
- 143 4. Total bilirubin

## 144 18.6 Reporting of Living Donor Events

145 Recovery hospitals must report these living donor events through the Improving Patient Safety Portal or the OPTN  
 146 Contractor according to *Table 18-4* below.

147

148 **Table 18-4: Living Donor Event Reporting**

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	Improving Patient Safety Portal and the OPTN Contractor	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living liver donor is listed on the liver wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN Contractor	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

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150 The Membership and Professional Standards Committee will review all cases reported according to *Table 18-4*  
 151 above and report to the OPTN Board of Directors.

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## Appendix A: Acronyms, Terms, and Descriptions

Acronym	Term(s)	Description
	Data cleaning, Data cleansing	The process of detecting and correcting inaccurate or corrupt records from a record set, table, or database
	Data quality assurance	The process of data profiling to discover inconsistencies and other anomalies in the data, as well as performing data cleaning activities
	Submission	The act of providing data that is considered to be accurate and final
SRTR	Scientific Registry of Transplant Recipients	Contractor responsible for providing statistical and other analytic support to the Organ Procurement and Transplantation Network.
TIEDI®	Transplant Information Electronic Data Interchange	Electronic data collection worksheets found in UNet <sup>SM</sup>
UNet <sup>SM</sup>		Proprietary computer system including TIEDI, the waiting list, and match runs
	Validation, Validate, Validated	The process of ensuring data have undergone data cleansing to ensure the values are correct and useful. Data validation is often performed using computer routines
VCA	Vascularized Composite Allografts	Transplant involving any body parts that meet the following nine criteria: <ol style="list-style-type: none"> <li>1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.</li> <li>2. Containing multiple tissue types.</li> <li>3. Recovered from a human donor as an anatomical/structural unit.</li> <li>4. Transplanted into a human recipient as an anatomical/structural unit.</li> <li>5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).</li> <li>6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);</li> <li>7. Not combined with another article such as a device.</li> <li>8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.</li> <li>9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.</li> </ol>

## Appendix B: Generation Information Associated With TIEDI Data Collection Instruments and Submission Requirements

<b>Title</b>	<b>Responsible Member</b>	<b>Generating Event</b>	<b>Generation Frequency</b>	<b>Generation Timing</b>	<b>Submission Requirement Within...</b>
Deceased Donor Registration	OPO	Organ Disposition form completed in DonorNet	Once	After organ recovery	30 days of generation date
Donor Histo-compatibility	Histo Lab	Organ Disposition form completed in DonotNet Living donor status update completed	Once	Post-transplant	30 days after DDR submission
Living Donor Follow-up	TxC	6 months after transplant	6 months; 1 year; 2 years	Post-transplant	60 days of generation date
Living Donor Registration	TxC	Living donor status update completed Candidate removed from waiting list using donor's DonorID	Once	Post-transplant	60 days of generation date
Recipient Histo-compatibility	Histo Lab	Recipient status update completed Living donor status update completed	Once	Post-transplant	30 days after waiting list removal because of transplant
Transplant Candidate Registration	TxC	Candidate added to waiting list	Once	Pre-transplant	30 days of generation date
Transplant Recipient Follow-up	TxC	Transplant date entered removing recipient from waiting list	6 months; 1 year; Annually	Post-transplant	30 days after 6-month and annual anniversary of transplant until death or graft failure; or 14 days from notification of death or graft failure
Transplant Recipient Registration	TxC	Recipient removed from waiting list	Once	Post-transplant	60 days after waiting list removal

Note: Histo Lab – Histocompatibility Laboratory; OPO – Organ Procurement Organization; TxC – Transplant Program

Source: OPTN *Policy 18: Data Submission Requirements* and discussions with UNOS staff.

## Appendix C: Advantages and Disadvantages Associated With Implementing a Process for Changing Officially Submitted Data

Alternative	Advantages	Disadvantages
Prior review and approval by the OPTN Contractor required before member may change previously submitted data	<ul style="list-style-type: none"> <li>• Changes permitted only under circumstances defined by the Committee or OPTN contactor</li> <li>• Public comment can obtain feedback about legitimacy of circumstances under which changes will be permitted</li> <li>• Could be modeled after Regional Review Board process</li> <li>• Underscores importance of submitting accurate and timely by the due date</li> <li>• Establishes a clear process for changing submitted data</li> </ul>	<ul style="list-style-type: none"> <li>• Requires new project form because proposal goes beyond scope of this project</li> <li>• Requires additional staffing or assignment of additional duties to existing staff to review and adjudicate requests</li> <li>• Requires additional programming to create a Regional Review Board-like process</li> <li>• Subjectivity of change requests positions the Committee and/or OPTN contractor for charges of bias and inconsistency</li> <li>• Database may contain known errors because change requests do not meet established criteria</li> <li>• Volume and complexity of change requests could delay resolutions</li> </ul>
Prior review and approval by the Data Advisory Committee or designated sub-committee required before member may change previously submitted data	<ul style="list-style-type: none"> <li>• Changes permitted only under circumstances defined by the Committee or OPTN contactor</li> <li>• Public comment can obtain feedback about legitimacy of circumstances under which changes will be permitted</li> <li>• Could be modeled after Regional Review Board process</li> <li>• Underscores importance of submitting accurate and timely by the due date</li> <li>• Establishes a clear process for changing submitted data</li> </ul>	<ul style="list-style-type: none"> <li>• Requires new project form because proposal goes beyond scope of this project</li> <li>• Requires additional staffing or assignment of additional duties to existing staff to review and adjudicate requests</li> <li>• Requires additional programming to create a Regional Review Board-like process</li> <li>• Subjectivity of change requests positions the Committee and/or OPTN contractor for charges of bias and inconsistency</li> <li>• Database may contain known errors because change requests do not meet established criteria</li> <li>• Volume and complexity of change requests could delay resolutions</li> <li>• Requires additional staffing or assignment of additional duties to existing staff to collect, review, and summarize members' requests for the Committee</li> </ul>

<b>Selected Proposal</b>	<b>• Advantages</b>	<b>• Disadvantages</b>
Members make changes and provide explanation for change and name of individual at member institution approving change	<ul style="list-style-type: none"><li>• Improves data accuracy</li><li>• Requires members to explain reason for change and assign responsibility for change to an individual at the institution</li><li>• Creates data warehouse of change reasons</li><li>• Permits analysis and reporting of submitted information</li><li>• Permits detailed reporting of member behavior, including change reasons, frequency of changes, and elements being changed</li><li>• Does not delay data changes</li><li>• Increases member oversight of data changes</li><li>• Position titles in EMPIR can be associated with specific individuals at member institutions who are likely responsible for data quality</li></ul>	<ul style="list-style-type: none"><li>• Changes to submitted data still permitted</li><li>• Process may not provide expected level of deterrence</li><li>• Level of detail needed to adequately analyze member behavior is unclear</li><li>• Maintenance of position titles used to identify individuals with data quality responsibilities could require extensive resources</li></ul>