

## *Notice of OPTN Policy Changes*

# Conclude Relaxation of Data Submission Requirements for Follow-Up Forms

**Sponsoring Committee:**

**Executive Committee**

**Policies Affected:**

***18.1.B: Timely Submission of Certain Data***

***18.1.B.i: Retrospective Data Collection during COVID-19 Emergency***

***18.2: Timely Collection of Data***

***18.5.A: Reporting Requirements after Living Kidney Donation***

***18.5.B: Reporting Requirements after Living Liver Donation***

**Approval Date:**

**March 1, 2021**

**Effective Date:**

**April 1, 2021**

### **Purpose of Policy Changes**

The Relaxation of Data Submission Requirements policy changes were enacted to address the effects of the COVID-19 pandemic on the transplant community. At this time, the transplant community is adapting and improving its ability to collect and report follow up data on their transplant recipients and living donors. This change will sunset the temporary measures addressing this data collection and establish a path for the collection of data from that period.

### **Proposal History**

- Relaxation of Data Submission Requirements was approved as an emergency action, effective March 13, 2020
- Relaxation of Data Submission Requirements was published for public comment August 4-October 1, 2020
- The Board of Directors continued the Relaxation of Data Submission Requirements at their December 2020 meeting, and committed to continue to review and repeal when appropriate
- This proposal sunsetting those changes and setting forth a timeline for retrospective data submission was approved on March 1, 2021

### **Summary of Changes**

This action sunsets the data collection changes included in the Relaxation of Data Submission Requirements Board action, effective April 1, 2021, and adds a timeline for submitting Transplant Recipient Follow-Up Forms (TRF), Living Donor Follow-Up (LDF) forms, and Post-Transplant Malignancy (PTM) forms that were not submitted while those changes were in place.

## Implementation

- Effective April 1, 2021, TRF, LDF, and PTM forms due will no longer be placed in amnesty status automatically.
- Transplant hospitals will be required to report transplant recipient deaths and graft failures on the TRF within 14 days from notification of the death or graft failure (rather than the longer 30-day period allowed during the relaxed standards).
- TRF, LDF and PTM forms that were placed in amnesty status prior to April 1, 2021 will need to be completed by July 1, 2021.

## Affected Policy Language<sup>1</sup>

New language is underlined (example) and language that is deleted is struck through (~~example~~).

### 18.1.B Timely Submission of Certain Data

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

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

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor Histocompatibility (DHS)</i>	60 days after the DHS record is generated	Each living and deceased donor
Histocompatibility Laboratory	<i>Recipient Histocompatibility (RHS)</i>	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, pancreas, or VCA transplant recipient typed by the laboratory
OPO	<i>Death Notification Registration (DNR)</i>	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

<sup>1</sup> The language approved in this action is based on the most recent language approved by the OPTN Board of Directors; however, some of this language is pending implementation of the proposal [Modify Data Submission Policies](#). For the most current policies in effect, including the current timeframes for data submission, please visit the [OPTN Policies page](#). If you have any questions, please contact [member.questions@unos.org](mailto:member.questions@unos.org).

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN:</i>	<i>Within:</i>	<i>For:</i>
OPOs	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential Transplant Recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, pancreas, or VCA that is offered to a potential 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>	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
Recovery Hospitals	<i>Living Donor Feedback</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>	90 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN:</i>	<i>Within:</i>	<i>For:</i>
Recovery Hospitals	<i>Living Donor Follow-up (LDF)</i>	<p><del>Either:</del></p> <ul style="list-style-type: none"> <li>90 days after the six-month, 1-year, and 2-year anniversary of the donation date or</li> <li><del>As determined possible by the transplant hospital during the COVID-19 emergency.</del></li> </ul>	<p>Each living donor organ recovered at the hospital</p> <p>This does not apply to domino donor, and non-domino therapeutic donor organs.</p> <p><del>Non-submission of the full LDF is acceptable during the COVID-19 emergency</del></p>
Transplant hospitals	<i>Organ Specific Transplant Recipient Follow-up (TRF)</i>	<p><del>Either of the following:</del></p> <ul style="list-style-type: none"> <li>90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or<sup>2</sup> <del>as determined possible by the transplant hospital during the COVID-19 emergency</del></li> <li><del>30 14</del> days from notification of the recipient's death or graft failure</li> </ul>	<p>Each recipient followed by the hospital</p> <p><del>Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.</del></p>
Transplant hospitals	<i>Organ Specific Transplant Recipient Registration (TRR)</i>	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital

<sup>2</sup> This language ("90 days after...until the recipient's death or graft failure or") was struck in error during the OPTN Executive Committee's March 1, 2021 vote to approve the proposal "Conclude Relaxation of Data Submission Requirements for Follow Up Forms." The Executive Committee approved a correction, effective April 26, 2021.

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN:</i>	<i>Within:</i>	<i>For:</i>
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Waiting List Removal for Transplant</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, pancreas, or VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient Malignancy (PTM)</i>	<p><del>Either:</del></p> <ul style="list-style-type: none"> <li>• 30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up form</i> <del>or</del></li> <li>• <del>As determined possible by the transplant hospital during the COVID-19 emergency.</del></li> </ul>	<p>Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.</p> <p><del>Non-submission is acceptable during the COVID-19 emergency.</del></p>
Transplant hospitals	<i>Transplant Candidate Registration (TCR)</i>	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, pancreas, or VCA candidate on the waiting list or recipient transplanted by the hospital

### 18.1.B.i Retrospective Data Collection during COVID-19 Emergency

<u>The following member</u>	<u>Must submit the following instruments to the OPTN</u>	<u>For the following</u>	<u>By</u>
<u>Recovery Hospitals</u>	<u><i>Living Donor Follow-up (LDF)</i></u>	<u>Living donors with forms due during the period of March 13, 2020 through March 31, 2021.</u>	<u>July 1, 2021</u>

<u>Transplant hospitals</u>	<u>Organ Specific Transplant Recipient Follow-up (TRF)</u>	<u>Recipients with forms due during the period of March 13, 2020 through March 31, 2021.</u>	<u>July 1, 2021</u>
<u>Transplant hospitals</u>	<u>Recipient Malignancy (PTM)</u>	<u>Recipients with forms due during the period of March 13, 2020 through March 31, 2021.</u>	<u>July 1, 2021</u>

## 18.2 Timely Collection of Data

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

**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.
Recovery hospital	<i>Living donor follow-up (LDF)</i>	<p>Either:</p> <ul style="list-style-type: none"> <li>• 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or</li> <li>• <del>As determined possible by the transplant hospital during the COVID-19 emergency.</del></li> </ul> <p><del>Non-submission is acceptable during the COVID-19 emergency.</del></p>

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

During the COVID-19 emergency, these policy requirements are suspended. LDF forms due between March 13, 2020 and March 31, 2021 are exempt from the requirements in this section.

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. Regularly administered dialysis as an ESRD patient
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**

During the COVID-19 emergency, these policy requirements are suspended. LDF forms due between March 13, 2020 and March 31, 2021 are exempt from the requirements in this section.

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

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

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

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

1. Alanine aminotransferase
2. Alkaline phosphatase
3. Platelet count
4. Total bilirubin