OPTN

Public Comment Proposal

Update and Improve Efficiency in Living Donor Data Collection

OPTN Living Donor Committee

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Update and Improve Efficiency in Living Donor Data Collection

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Sponsoring Committee:	*Living Donor*
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Executive Summary

The OPTN Living Donor Committee (the Committee) proposes a transformative initiative to modernize and enhance the collection of data related to living organ donation. This proposal responds to a gap in the current system: while the benefits of living donation are well established, there remains a lack of comprehensive, long-term data on the physical, psychosocial, and economic outcomes for living donors. This expanded knowledge is essential for several critical purposes: improving the informed consent process, refining clinical practices and policies, and enhancing efficiency and safety. Existing OPTN policies require transplant programs to inform prospective donors about potential risks of donating an organ, yet the evidence base to support these discussions is limited due to the required follow-up period

ending at two years and the absence of a comparator group to accurately assess the safety of living donation. To address these challenges, the Committee has developed a proposal that aims to improve the efficiency, accuracy, and scope of data collection, and better understand the barriers to living donation. This includes capturing information earlier in the donation process, incorporating data on potential donors who do not donate, and transitioning long-term follow-up responsibilities to the Scientific Registry of Transplant Recipients (SRTR). The Committee focused on collecting only the most pertinent data, consisting of both required and optional fields, in a new form, to better understand long-term outcomes and empower living donor safety. Together, these efforts are designed to support more informed decision-making, enhance donor protections, and promote equitable access to living donation.

Purpose

The purpose of this project is to improve understanding regarding barriers and access to living donation and to expand knowledge and data collection about long-term outcomes of living donation.

While the benefit of living organ donation for recipients is clear and well demonstrated, the long-term impact of donation on a living donor's psychosocial, economic, and physical wellbeing has yet to be fully understood or studied.[1] OPTN policy requires transplant programs to inform living donors of the potential known risks to their psychosocial, economic, and physical well-being by donating.[2] Longer-term data collection on living donors may broadly and positively influence living donation. Lifetime follow-up of living donors may increase knowledge regarding the risks and benefits of living organ donation to the living donor. Additionally, long-term follow-up may enable analysis regarding emotional and psychosocial benefits for living donors, some of which has been documented in previous research.[3,4,5] It may also safeguard living donors' long-term wellness and safety by providing data to identify risk factors and long-term outcomes, which could subsequently inform living donor policy. Achieving this may allow for a more evidence-based approach to broadening opportunities for living donation, while also protecting living donors.

There is consensus across the transplant community that long-term data on living donation is necessary, and that understanding the risk and outcomes attributable to donation requires data collection on similar non-donors.[6,7,8,9] Notably, a recent multi-stakeholder consensus conference, where a quarter of participants were transplant patients and living donors, was held to prioritize what data were most valuable to the transplant community.[10] The conference participants felt that collecting long-term data

[1] OPTN/SRTR Annual Data Report. https://www.srtr.org/reports/optnsrtr-annual-data-report/ (Accessed June 6, 2025).
[2] OPTN Policy 14.3: Informed Consent, Table 14-1: Requirements for Living Donor Informed Consent (May 5, 2025).
[3] Van Pilsum Rasmussen S., Robin, M., Saha, A., Eno, A., et al. "The Tangible Benefits of Living Donation: Results of a Qualitative Study of Living Kidney Donors." Transplant Direct. 2020 Nov 10;6(12):e626. doi: 10.1097/TXD.0000000000001068.
[4] Rodrigue, J., Paek, M., Whiting, J., et al. "Trajectories of perceived benefits in living kidney donors: association with donor characteristics and recipient outcomes." Transplantation. 2014; 977762–768.
[5] Clemens, K., Thiessen-Philbrook, H., Parikh, C., et al.; "Donor Nephrectomy Outcomes Research (DONOR)."
[6] Lentine KL, Kasiske BL, Levey AS, Adams PL, Alberú J, Bakr MA, Gallon L, Garvey CA, Guleria S, Li PK, Segev DL, Taler SJ, Tanabe K, Wright L, Zeier MG, Cheung M, Garg AX. KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. Transplantation. 2017 Aug;101(8S Suppl 1):S1-S109. doi: 10.1097/TP.0000000000001769. PMID: 28742762; PMCID: PMC5540357.
[7] Snyder JJ, Schaffhausen CR, Hart A, Axelrod DA, Dils D, Formica RN Jr, Gaber AO, Hunt HF, Jones J, Mohan S, Patzer RE, Pinney SP, Ratner LE, Slaker D, Stewart D, Stewart ZA, Van Slyck S, Kasiske BL, Hirose R, Israni AK. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." Am J Transplant. 2023 Jul;23(7):875-890. doi: 10.1016/j.ajt.2023.03.012. Epub 2023 Mar 21. PMID: 36958628.
[8] Lentine KL, Waterman AD, Cooper M, Nagral S, Gardiner D, Spiro M, Rela M, Danovitch G, Watson CJE, Thomson D, Van Assche K, Torres M, Domínguez-Gil B, Delmonico FL; Donation Workgroup Collaborators. "Expanding Opportunities for Living Donation: Recommendations From the 2023 Santander Summit to Ensure Donor Protections, Informed Decision Making, and Equitable Access. Transplantation." 2025 Jan 1;109(1):22-35. doi: 10.1097/TP.0000000000005124. Epub 2024 Oct 22. PMID: 39437374; PMCID: PMC12077664.
[9] Lentine KL, Lam NN, Segev DL. "Risks of Living Kidney Donation: Current State of Knowledge on Outcomes Important to Donors." Clin J Am Soc Nephrol. 2019 Apr 5;14(4):597-608. doi: 10.2215/CJN.11220918. Epub 2019 Mar 11. PMID: 30858158; PMCID: PMC6450354.
[10] Snyder JJ, Schaffhausen CR, Hart A, et al. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." *Am J Transplant*. 2023;23(7):875-890. doi:10.1016/j.ajt.2023.03.012

on living donor outcomes and defining donation attributable risks through proper comparisons is a moral and ethical obligation.[11]

Collecting data to understand long-term outcomes of living donation will aid in the OPTN's goal of improving the informed choice of prospective living donors, and the safety, protection, and follow-up of all living donors.[12] This will be achieved through a collaboration between the Scientific Registry of Transplant Recipients (SRTR) and the OPTN.[13] Collecting data on potential living donors who meet with a transplant team member, including those who ultimately do not donate, will provide a comparator group to analyze the risks and benefits attributable to live organ donation. Living donors, or those interested in donating, tend to be healthier due to the rigorous selection process.[14,15] Therefore, comparing living donors against the general population may yield misleading conclusions on the long-term challenges they could face. Furthermore, collecting data on reasons for not donating will allow for analysis to better understand how to improve equitable access to living donation, with the intent to reduce barriers to donation. This proposal will require the OPTN to collect data earlier in the living donation process to create a baseline for long term data collection. Collection of this data by the OPTN will enable the SRTR to expand upon its established Living Donor Collective to collect voluntary follow-up to assess long-term outcomes of potential living donors who do not donate and living donors.

Background

This proposal has emerged as an ongoing priority of the transplant community, reflecting years of consideration, deliberation, and public engagement focused on increased efforts to determine long-term living donor outcomes and opportunities to improve long-term data collection. In 2021 and 2022, the Living Donor Committee presented reports to the OPTN Board of Directors that summarized their deliberations on the importance of long-term living organ donor follow-up.[16]

At the beginning of 2023, the Committee concluded that a project, in collaboration with the SRTR, to require transplant programs to report data to the OPTN on potential living donors would be most impactful. Additionally, this is aligned to Task 5, which HRSA established with

[11] Ibid.
[12] OPTN Strategic Plan. https://optn.transplant.hrsa.gov/about/strategic-plan/goal-1/. (Accessed June 9, 2025).
[13] The OPTN and the SRTR perform different roles in living donor data collection. The work of both the OPTN and SRTR are performed under separate contracts with the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (HHS). The OPTN requires that transplant programs register all living donors. The OPTN requires data submission on living donor at the time of discharge via the LDR and follow-up after the live donation via the LDF. The SRTR Living Donor Collective is a national living donor registry which seeks to register all individuals that undergo evaluation for living donation in order to perform long-term follow up of both living donors and living donor candidates. This began as a pilot program and in 2020, HRSA directed the SRTR to expand the Collective to include all living donor programs. More information about this relationship is described in the Committee's concept paper *Concepts for a Collaborative Approach to Living Donor Data Collection*. https://optn.transplant.hrsa.gov/media/ee5jqj23/ldc_living-donor-data-collection_concept-paper_pcsummer2023.pdf (accessed July 1, 2025).
[14] NKF roadmap: Lentine KL, Pastan S, Mohan S, Reese PP, Leichtman A, Delmonico FL, Danovitch GM, Larsen CP, Harshman L, Wiseman A, Kramer HJ, Vassalotti J, Joseph J, Longino K, Cooper M, Axelrod DA. A Roadmap for Innovation to Advance Transplant Access and Outcomes: A Position Statement From the National Kidney Foundation. Am J Kidney Dis. 2021 Sep;78(3):319-332. doi: 10.1053/j.ajkd.2021.05.007. Epub 2021 Jul 27. PMID: 34330526.
[15] Lentine KL, Waterman AD, Cooper M, Nagral S, Gardiner D, Spiro M, Rela M, Danovitch G, Watson CJE, Thomson D, Van Assche K, Torres M, Domínguez-Gil B, Delmonico FL, Donation Workgroup Collaborators. "Expanding Opportunities for Living Donation: Recommendations From the 2023 Santander Summit to Ensure Donor Protections, Informed Decision Making, and Equitable Access. Transplantation." 2025 01 01; 109(1):22-35. PMID: 39437374
[16] Meeting Summary for December 14, 2022, OPTN Living Donor Committee.

the SRTR in September 2020 with the goal to identify metrics to assess national transplantation system performance and support informed decision-making by critical audiences, which includes potential living donors.[17] The Committee determined it was important to collect data on potential living donors who did not donate because it will allow for an appropriate comparator group as well as provide analysis on barriers and access to living donation. SRTR was tasked with managing and expanding the Living Donor Collective (the Collective), a national living donor registry.[18] The Committee then worked to develop requirements for the OPTN collection and reporting of potential living donor and decision data, which would then allow for the SRTR to follow up long-term on potential living donors who did not donate in addition to living donors on a national level.

During the first half of 2023, the Committee developed the concepts for this project and published a concept paper for public comment. The concept paper detailed a future state of living donor data collection and requested feedback on the topic and the role of OPTN under this collaborative approach.[19] The Committee received support from the community regarding the concepts as well as constructive feedback on how to operationalize them.

The Committee additionally recognized the need for granular review of existing OPTN forms to ensure accurate and relevant data collection. Updates to living donor data collection improve the quality, usefulness, and trustworthiness of OPTN data by evaluating the relevancy, currency, and accuracy of OPTN living donor data. Data collection forms have not been consistently modified since initial development, and a comprehensive review of all OPTN living donor data collection has never been performed.

Following broad support from the June 2023 concept paper and the OPTN Board of Directors, the Committee decided to create a two-phased project to, first, collect donation decision data on all potential living donors that do not proceed to donation and, second, to perform a comprehensive review of all OPTN living donor data collection on current OPTN forms. The project included removal of the OPTN two-year follow-up of living donors, transitioning this role to the SRTR Living Donor Collective. The OPTN will retain the six-month and one-year follow-up requirement to continue to capture any patient safety concerns, while the existing requirement that adverse events within the two years following donation be reported by recovery hospitals will remain.[20] The SRTR will administer direct voluntary follow-up after the one-year mark of both living donors and potential living donors that do not go on to donate. Because both ideas would involve updating and changing data collection, and therefore, require Office of Management and Budget approval and changes to the OPTN Computer System, the Committee thought it appropriate to pursue these efforts concurrently to be efficient. The Policy Oversight Committee supported the approach to combine these efforts. [21]

The proposed project was then considered by the OPTN Executive Committee in June of 2024, and members approved the project goals and affirmed its importance to the OPTN but requested that the

[17] The Task 5 Initiative: Identifying Metrics to Support Informed Decision-Making by Critical Audiences. https://www.srtr.org/about-srtr/the-task-5-initiative/ (accessed June 9, 2025).
[18] SRTR Living Donor Collective. https://www.livingdonorcollective.org/ (accessed June 9, 2025).
[19] Concepts for a Collaborative Approach to Living Donor Data Collection. OPTN Living Donor Committee, June 2023, https://optn.transplant.hrsa.gov/media/ee5jqj23/ldc_living-donor-data-collection_concept-paper_pcsummer2023.pdf (accessed May 5, 2025).
[20] A recovery hospital is proposed to be defined as "A transplant hospital that performs the surgery to recover living donor organs for transplantation," found in the Policy Language section of this proposal.
[21] Meeting Summary for June 13, 2024, OPTN Policy Oversight Committee, https://optn.transplant.hrsa.gov/media/4urfwhkn/06132024-poc-meeting-summary.pdf (accessed June 9, 2025).

project timeline be shortened by six months, to be submitted on an expedited timeline. The Committee discussed how to accomplish the project goals in a shorter timeline. Through these discussions, members identified that full review of current and new OPTN living donor data collection could not be accomplished on an expedited timeline, thus making a phased approach necessary. The Committee reached consensus to accomplish the establishment of new data collection and transition of long-term follow-up to the SRTR in the first phase, and complete necessary updates to OPTN forms in Phase 2 that will go out for public comment after Phase 1.[22]

Phase 1 includes removal of OPTN two-year follow-up, creation of a new form and modification of existing OPTN forms to collect data on potential living donors using demographic and clinical information, and collect decision data. The Committee's intent was to establish the minimum number of changes to enable the goals of the data collection in this first phase.

Phase 2, a subsequent proposal, will include granular review efforts to update existing OPTN living donor collection and build off of Phase 1 to add necessary enhancements to data collection of potential living donors who do not go on to donate.

From June 2024, the Committee worked to create Phase 1 of the project by reviewing SRTR Living Donor Collective candidate registration elements and identifying necessary elements to add to the OPTN forms. The Committee also formed a workgroup to focus on reviewing and operationalizing a new OPTN living donor decision data form developed from the SRTR's decision data form. The workgroup included representatives of other OPTN committees, including the Data Advisory Committee (DAC), Transplant Administrators Committee, Transplant Coordinators Committee, Kidney Transplantation Committee, and Liver and Intestinal Organ Transplantation Committee. Additional collaboration with the SRTR to ensure the data collection can be aligned with the existing SRTR Living Donor Collective framework, and review of all data elements with the DAC occurred during proposal development.

At the request of the OPTN Board of Directors, the Committee also submitted a report in June 2024 to identify opportunities to enhance living donation.[23] The report included Committee deliberations from December 2023 – June 2024 to identify existing roadblocks, challenges with current data collection, ideas to optimize the system to promote living donation, and opportunities for collaboration and innovations to improve living donation. The report recommended completion of an enhanced data collection project as foundational work to further understand how to enhance living donation.

The SRTR participated in the development of this proposal as active members of the workgroup and Living Donor Committee meetings. They presented findings from the Living Donor Collective pilot and shared their current data collection methods, including the reasons candidates chose not to donate. Their analysis of free text reasons for not donating, particularly for kidney and liver donations, assisted the workgroup in identifying reasons for inclusion as data element options and define the data elements for the new form. Throughout the review process, the SRTR provided feedback on the proposed data elements, highlighting information they deemed essential for long-term follow-up.

[22] Meeting Summary for June 14, 2024, OPTN Executive Committee,https://optn.transplant.hrsa.gov/media/3tmprm3q/20240614_executive-committee_summary.pdf (accessed May 5, 2025).
[23] *Report to the Board of Directors on Enhancing Living Donation*, OPTN Living Donor Committee, June 17, 2024, https://optn.transplant.hrsa.gov/media/x0ml5vjb/ldc_concept-paper_boardreport_dec23.pdf (accessed May 5, 2025).

From June 2024 to present, the Committee worked on the first phase of this project by defining when data collection on potential living donors should begin, creating a new form to capture why interested individuals do not proceed to donation, creating a workflow, and identifying the relevant data elements to be included for potential living donors who do not go on to donation. In this work, the Living Donor Committee collaborated with the SRTR, the OPTN Data Advisory Committee, and a workgroup with additional expertise.

Current OPTN Data Collection: Living Donors

To create a new form of data collection for potential living donors, the Committee and its collaborators considered current OPTN data collection and how to integrate a new form. This section describes current OPTN data collection, to better understand the proposed changes.

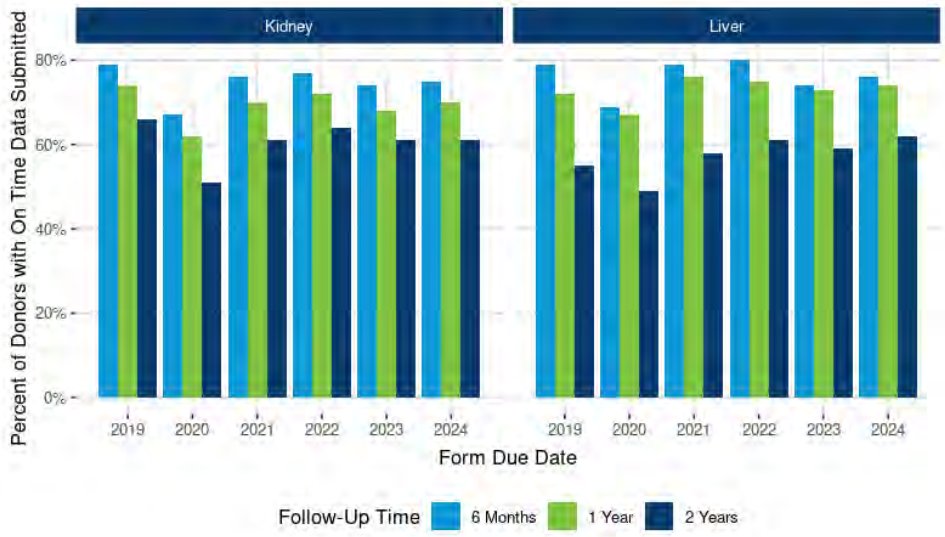
The OPTN requires recovery hospitals to collect and report data on living donors.[24] The first required data reporting on approved living donors occurs via the Living Donor Feedback (Add Donor) form. The purpose of this form is to generate an identification number for the living donor. The Living Donor Feedback (Add Donor) form collects baseline data such as blood type, sex, date of birth, and organ type and must be submitted prior to the donation surgery.[25] The Living Donor Feedback form is later populated with recipient information for donated organs once transplanted. Generally, the Living Donor Feedback (Add Donor) data is submitted once a living donation is scheduled. In the unlikely event that a candidate is not transplanted, the hospital must update the feedback form directly indicating the outcome. Therefore, while the Living Donor Feedback (Add Donor) form collects data prior to the donation event, it remains specific to approved living donors, and not potential living donors.

The Living Donor Registration (LDR) form is the next required data reporting. The purpose of the LDR is to collect information on the pre- and peri-operative period of the donation event, as well as demographic data and is the most extensive data on living donors. The LDR demographic data collection includes elements such as education level, health insurance, and citizenship status. Pre-donation and post-donation clinical data as well as surgical information is collected on all living donors, and there are additional data elements specific to the organ donated for living kidney, liver, lung, and uterus donors. The LDR must be completed within 90 days after the recovery surgery outcome is reported to the OPTN.[26]

Following the pre- and post-operative data that is collected via the LDR, the OPTN requires collection and reporting of living donor follow-up data via the Living Donor Follow-up (LDF) form. The purpose of this form is to collect data to inform the experience, safety, and health implications for living donors by comparing pre-donation data to post-donation data. OPTN policy requires the LDF form to be submitted for each living donor within 90 days of the six-month, one-year, and two-year anniversaries of the donation date.[27] The data collected in the LDF form include living donor status, organ-specific clinical information, and complications. Of follow-up forms due in 2024 **(Figure 1**), as of 4/4/2025, the one-year follow-up was submitted on time for 70 percent of living kidney donors and 74 percent of living liver donors.

[24] OPTN Policy 18.1: Data Submission Requirements (May 5, 2025).
[25] OPTN Policy 18.1: Data Submission Requirements, Table 18-1: Data Submission Requirements (May 5, 2025).
[26] Ibid.
[27] Ibid.

Figure 1: OPTN Liver and Kidney Follow-Up Rates by LDF Due Date

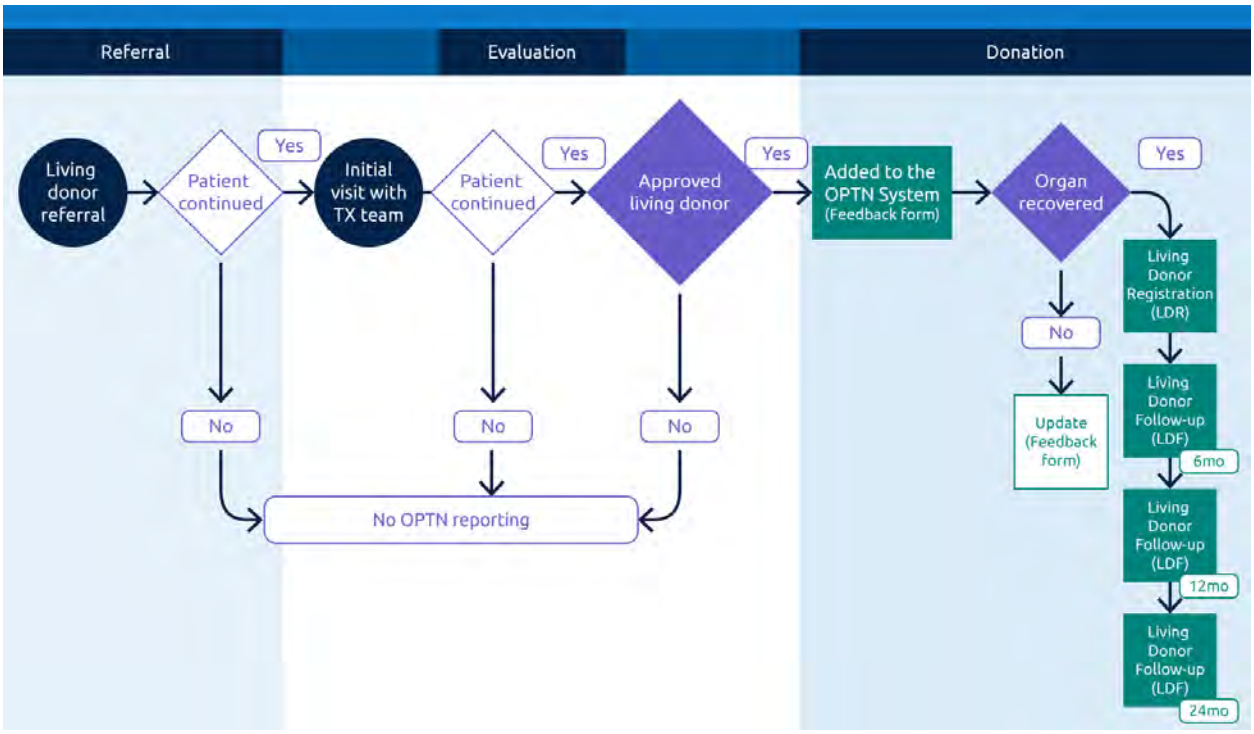


The OPTN does not currently collect any data from recovery hospitals on potential living donors that do not go on to donation, except for required reporting if a living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.[28] Under this circumstance, both the Feedback and LDR forms are completed for the patient.

Below (**Figure 2**) is a diagram depicting the current OPTN data collection process, including required forms, for living donation.

[28] OPTN Policy 18.5.B: Required Reporting of Living Donor Events by Recovery Hospitals, Table 18-4: Living Donor Event Reporting (May 5, 2025).

Figure 2: OPTN Living Donation Collection – Current State



SRTR Living Donor Collective and Data Reporting

The SRTR is required to support ongoing evaluation of scientific and clinical status of solid organ transplantation pursuant to section 373 of the Public Health Service Act.[29] The SRTR is responsible for providing statistical and other analytic support to the OPTN for purposes of policy development and evaluation, system performance metrics, economic analysis, and preparation of recurring and special reports to Congress.[30] Additionally, the SRTR piloted a living donor registry per contract requirement with HRSA. The SRTR aims to study the long-term outcomes of living organ donation via their living donor registry.[31] The project, named the Living Donor Collective, began as a pilot including ten transplant programs to develop the necessary infrastructure and processes, to assess feasibility of living donor candidate registration by transplant programs, with an ultimate plan to include all living donor transplant programs in the United States.[32, 33]

The idea of establishing a national registry to track long-term data on living donors has been extensively discussed by the community. In 2000, the Living Donor Consensus Conference supported the creation of

[29] Driven to Make a Difference: Mission, Vision, and Values, Scientific Registry of Transplant Recipients., https://www.srtr.org/about-srtr/mission-vision-and-values/ (accessed May 5, 2025).
[30] Ibid.
[31] Who We Are, Living Donor Collective: An SRTR Initiative, https://livingdonorcollective.org/about-ldc/who-we-are/ (Accessed May 5, 2025).
[32] While "candidates" has a specific meaning in OPTN policy in referring to individuals registered on the waiting list for a transplant, SRTR uses the term "living donor candidates" based on the 2017 KDIGO Living Donor Guideline for individuals evaluated for living donation. The term is used here to accurately reflect the language used in the registry.
[33] Kasiske BL, Asrani SK, Dew MA, Henderson ML, Henrich C, Humar A, Israni AK, Lentine KL, Matas AJ, Newell KA, LaPointe Rudow D, Massie AB, Snyder JJ, Taler SJ, Trotter JF, Waterman AD, Living Donor Collective. "The Living Donor Collective: A Scientific Registry for Living Donors." Am J Transplant. 2017;17(12):3040-3048.

a Live Organ Donor Registry aimed at collecting demographic, clinical, and outcome data for all living donors.[34] This endorsement was partly driven by the limited understanding of the long-term effects of organ donation.

A recent contract required SRTR to formalize the registry as a national program and expand participation. While SRTR does not have the ability to require transplant programs to report data, they have the ability to interface directly with living donors and potential living donors. Both the OPTN and SRTR are public health authorities with established data use agreements which allow for disclosure of the minimum amount of protected health information necessary to ensure public health and safety.

All living donor transplant programs currently report data to the OPTN as required by policy, while several pilot programs report data to the SRTR voluntarily as part of the Living Donor Collective. While the OPTN collects peri-operative donation data and follow-up data at six-months, one-year, and two-years post-donation, the Living Donor Collective also collects annual follow-up data directly via surveys from both living donors and potential living donors that did not donate.[35] To enhance the dataset, OPTN and SRTR data can be linked with external data sources. Below, **Table 1-1** outlines the current data collection roles of both the OPTN and the SRTR Living Donor Collective.

If donation does not occur at a participating pilot program, the SRTR Living Donor Collective obtains voluntary data on reasons a living donor candidate did not donate. By registering living donor candidates, the Collective includes both living donors and a control population of individuals who underwent evaluation but did not donate.[36] This comparator group helps identify barriers to living donation and assess long-term outcomes.

The Living Donor Collective can link living donor candidate registry data to national death records to obtain data on deaths and causes of death among living donors. Living donor candidate registration data can also be linked to Centers for Medicare and Medicaid Services (CMS) reporting forms to better understand outcomes, along with OPTN data for transplant candidate listing and transplantation events (all solid organs). Other public and private data sources will also be used as available to obtain long-term follow-up information on registered living donor candidates and living donors.[37,38]

The SRTR follow up rates for living donors at the one-year anniversary of donation is 68 percent, as indicated below **(Table 1-2),** while the 12-month (required) follow-up rate for living kidney donors in the OPTN data are comparable at 70 percent (of the 6140 One-Year Kidney LDF's required in 2024, 4304 were submitted on time). Additionally, the SRTR rates include data from 10 participating living donor recovery hospitals, while the OPTN rates include all approved and active living donor programs (over

[34] Abecassis, M., Adams, M., Adams, P., et al. "Live Organ Donor Consensus Group: Consensus statement on the live organ donor," JAMA, (2000);284(22), 2919–2926. https://doi.org/10.1001/jama.284.22.2919.
[35] Kasiske BL, Lentine KL, Ahn Y, Skeans MA, Eberhard T, Folken C, Wainright J, Larkin L, Nystedt C. OPTN/SRTR 2020 Annual Data Report: Living Donor Collective. Am J Transplant. 2022 Mar;22 Suppl 2:553-586. doi: 10.1111/ajt.16983. PMID: 35266611.
[36] The SRTR uses the term "living donor candidates" while the Committee uses "potential living donors" to better distinguish between transplant donors and recipients.
[37] Lentine KL, Schnitzler MA, Xiao H, Saab G, Salvalaggio PR, Axelrod D, Davis CL, Abbott KC, Brennan DC. "Racial variation in medical outcomes among living kidney donors." N Engl J Med. 2010 Aug 19; 363(8):724-32. doi: https://doi.org/10.1056/NEJMoa1000950. PMID: 20818874; PMCID: PMC3041966.
[38] Lam NN, Garg AX, Segev DL, Schnitzler MA, Xiao H, Axelrod D, Brennan DC, Kasiske BL, Tuttle-Newhall JE, Lentine KL. "Gout after Living Kidney Donation: Correlations with Demographic Traits and Renal Complications." Am J Nephrol. 2015; 41(3):231-240. doi: https://doi.org/10.1159/000381291. PMID: 25896309; PMCID: PMC4522163.

100).[39] There is a SRTR follow-up rate of 44.6 percent at the one-year anniversary of a potential living donor's decision not to donate. There are no OPTN follow-up rates for potential living donors who do not donate, since collection of this data is not currently required.

The Committee aims to improve follow-up rates for living donors. It reviewed current OPTN follow-up rates at the two-year anniversary and compared them to the one-year follow-up rates for the Living Donor Collective provided by the SRTR. Despite low follow-up rates **(Table 1-2**) for the SRTR, the Committee considers that the SRTR's patient-centered approach can improve these rates.

Table 1-1: OPTN and Living Donor Collective Data Collection

OPTN	Living Donor Collective
Register living donors	**Registers living donor candidates***
Registration is mandatory for programs	**Registration is voluntary for programs**
Required follow-up for living donors at 6 months, 1 year, and 2 years	**Planned lifetime follow-up for living donor candidates and donors**

***Individuals who are pre-screened and come (in person or virtually) to a transplant center for living donor evaluation.**

Table 1-2: SRTR Follow-Up Rates (as of 4/8/2025) All Living Donors

1-Year Follow-Up Form	Number of Attempts	Decision to Donate Yes	Decision to Donate No
Completed	**Overall**	**1544 (68.0%)**	**785 (44.7%)**
Completed	**Initial automated email**	**722**	**193**
Completed	**2nd follow-up: phone/email**	**308**	**138**
Completed	**3rd follow-up: phone/email**	**156**	**198**
Completed	**Additional engagements**	**358**	**256**
Attempt ongoing (no response yet)	**Overall**	**728 (32.0%)**	**973 (55.3%)**

Overview of Proposal

The Committee integrated its review of current OPTN data forms and the data collected by the SRTR in this proposal to create a new living donor data collection form and conduct additional modifications to OPTN living donor data collection. The proposed changes include the following:

[39] The exact number of approved and/or active OPTN living donor recovery centers varies depending on the year, but overall rates include data of approved/active programs at any point in time.

- Remove the two-year living donor follow-up requirement from the OPTN and transfer voluntary follow-up to the SRTR, which follows the living donor and potential living donors long-term.
- Require transplant programs to submit new OPTN data collection on potential living donors who met in person with the transplant team, but did not donate.
- Recommend minimal additions and modifications of data elements on the Living Donor Feedback, Living Donor Registration, and Living Donor Follow-up data collection instruments to align with new data to be collected on potential living donors who did not donate.
- Change OPTN policy language to distinguish between living donors and potential living donors and incorporate data submission requirements for new data to be collected.

New Data Collection on Potential Living Donors Who Did Not Donate

The proposal would require recovery hospitals to collect information on potential living donors who did not proceed with donation to improve the understanding of living donation and its outcomes. The OPTN will share data on those who did not donate and their donation decisions with the SRTR to support their long-term follow-up efforts.

One of the primary objectives in collecting this new data is to understand why some potential living donors do not proceed with donation. By collecting data on donation decisions, including reasons for not proceeding, analysis of these barriers can occur. These data will identify major categories of barriers, provide insights into program-specific selection criteria, and highlight areas where additional support is needed during the evaluation process. The ultimate goal is to use these data to develop future policies or initiatives that offer specialized support to individuals facing barriers to living donation. Understanding the reasons behind a potential living donor's decision not to donate is fundamental to improving the living donation process and addressing potential inequities.

Additionally, collecting data on potential living donors who do not donate allows for the creation of a crucial comparator group for analyzing the long-term outcomes of living donors. Comparing prior living donors solely to the general population can be insufficient, as living donors tend to be healthier than the average population.[40] By collecting data on potential living donors who do not donate, especially those whose non-donation was due to reasons unrelated to their own health or the risks of donation (e.g., the intended recipient received a deceased donor organ or became too ill), a more suitable comparison group is established. This enables a robust analysis to understand the true differences in long-term health outcomes and risks associated with donating an organ versus not donating. Without this data from a non-donor cohort, questions about the risks and benefits of donation compared to not donating cannot be accurately answered.

The collection of data and long-term follow-up on potential living donors who do not donate, combined with enhanced long-term follow-up data collected by the SRTR on living donors, can contribute to a more comprehensive understanding of the long-term health and psychosocial outcomes of living donation. Providing potential living donors with more accurate and evidence-based information about potential long-term risks and benefits allows them to make truly informed decisions. The data can help refine organ-specific exclusion criteria, inform policies to protect potentially high-risk groups, and reduce variation in program-specific acceptance criteria by providing additional evidence regarding risk.

[40] Chen J, Bhattacharya S, Sirota M, et al. "Assessment of Post donation Outcomes in US Living Kidney Donors Using Publicly Available Data Sets." JAMA Netw Open. 2019;2(4):e191851. doi:10.1001/jamanetworkopen.2019.1851.

Transparency in center acceptance criteria is valued by the community.[41] By better understanding barriers and outcomes, the transplant process can be optimized and donor safety enhanced.

Requiring data collection on potential living donors who do not donate is a foundational step in a collaborative project to significantly improve the understanding of living donation. It allows the transplant community to better assess the true long-term impacts of donation by having a comparator group, and ultimately use this knowledge to enhance the safety, protection, informed consent, and equity of the living donation process for everyone involved. This represents a significant shift from the previous focus primarily on data collection from individuals who completed donation.

Framework for Data Collection on the New Living Donor Non-Donation Form

The new OPTN living donor decision data form, named the Living Donor Non-Donation form, will gather comprehensive information about potential living donors who do not proceed with donation. It includes several key sections, each serving a specific purpose to fulfill the proposal's goals.

Committee decisions to include specific data elements reflected consideration of the SRTR's Living Donor Collective decision data form, which includes an extensive multi-select list of reasons why a potential living donor did not proceed with donation. The Committee aimed to gather both baseline information on all potential living donors and details related to the specific reasons for non-donation decisions. While the SRTR Living Donor Collective form was reviewed and considered throughout the development of the new form, it was not used as a strict framework, allowing for flexibility and adaptation in the future as needed.

A New Living Donor Non-Donation Form

The Committee considered clarity in purpose and function when determining the new form name.[42,43] The name "Living Donor Non-Donation form" was overwhelmingly agreed upon because it clearly reflects that the form is used for individuals who were evaluated but did not donate, aligning with the terminology used in policy.

Below is an overview of the key sections included in the Living Donor Non-Donation form, while an unabridged chart of all sections, data elements and data definitions can be found at the end of this proposal.

Demographic Information: This section collects fundamental details about the potential living donor, such as name, social security number (SSN), contact information, ethnicity, race, citizenship, birth sex, organ type being considered (e.g., kidney, liver), and intended recipient details. Committee discussions also considered fields for previous evaluations or donations, with the possibility of determining these using SSN and patient IDs. Collecting demographic data is crucial for understanding barriers and access to living donation. It helps assess changes in the living donor population and supports the development of programs to increase donation among populations that donate less frequently. This information

[41] OPTN Ethics, Transparency in Program Selection White Paper. https://optn.transplant.hrsa.gov/media/eqbdiooe/transp-in-prg-selection_ethics_wp.pdf. December 2022 (Accessed June 9, 2025).
[42] Meeting Summary for April 23, 2025, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/jmhdaa33/20250423_livingdonorcomm_meeting-summary.pdf(accessed May 5, 2025).
[43] Meeting Summary for September 12, 2024, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/hcfeppdk/20240912_living-donor-meeting-summary.pdf (accessed May 5, 2025).

provides context for clinical data and insights into social determinants of health. Including SSN is important for linking data, especially if a donor is evaluated at multiple centers. Standardizing demographic fields with existing forms ensures consistency. The intended recipient information helps understand directed versus non-directed donation and how recipient factors might influence the process.

Clinical Information: This section captures baseline health information about the potential living donor, including family history, measurements like height and weight, substance use history (tobacco, nicotine, cannabis, alcohol), and various medical history details such as diabetes, hypertension (including pharmacological management), history of malignancy, Coronary Artery Disease (CAD), and other conditions. Labs may be included, though some might not be relevant if a donor exits evaluation early. Clinical data is necessary to analyze potential risk factors for living donors and to compare health outcomes between donors and potential donors who did not donate. Collecting this baseline information provides an appropriate comparator group for long-term outcomes analysis of living donors. It helps to understand the medical reasons why potential donors are declined, which are purposeful barriers intended to protect potential donors and recipients. This data contributes to expanding knowledge about long-term outcomes, improving informed consent, refining organ-specific exclusion criteria, developing policies to protect high-risk groups, and understanding variation in program-specific acceptance criteria.

Donation Decision Information: This central section captures the specific reasons a potential living donor did not donate. It includes a list of potential reasons for not proceeding with donation, with the ability to select multiple reasons. Examples of reason categories include medical/surgical contraindications, recipient-related factors (e.g., recipient received another transplant, recipient became too ill, recipient no longer a candidate), donor choice or withdrawal, logistical issues, financial barriers, psychosocial factors, incompatible match, or transfer to another center. The primary goal is to understand why some evaluated potential living donors do not proceed to organ recovery and donation. This helps analyze barriers to living donation, identify potentially modifiable factors, and provides insight into transplant program selection criteria. Understanding these reasons can inform policies and initiatives to support individuals facing particular barriers and help differentiate center-driven declines from candidate-driven decisions.

Surgical Addendum: This section is for specific, though rare, circumstances where a donation procedure is started but aborted. It captures information for cases where a potential living donor goes under anesthesia but the organ is not recovered. It includes details about the intended surgical plan and whether any incisions were made, including robotic procedures. Capturing these rare but reportable events ensures that data collection mirrors what is done for completed surgeries. These data are crucial for understanding potential complications that may arise even if the donation is not completed. Note that recovery hospitals will still submit the Living Donor Registration (LDR) form in the event the organ is recovered but not transplanted into a recipient.[44]

The inclusion of these major sections in the Living Donor Non-Donation form allows the OPTN to collect comprehensive information on potential living donors who do not donate. The Committee acknowledges that while there will not be data available to complete this form comprehensively, all of

[44] OPTN Policy 18.5.B: Required Reporting of Living Donor Events by Recovery Hospitals (March 27, 2025).

the relevant fields in the form will be mandatory to complete and not optional (there will be a "data not available" option for most elements). By creating any optional fields, the Committee feels that important and available data may not be collected. These data are essential for understanding barriers to living donation, creating an appropriate comparator group for rigorous long-term outcomes analysis, improving the informed consent process, refining clinical policies and practices, and ultimately enhancing the safety, protection, and equity of the living donation process.

Start of Data Collection on Potential Living Donors Who Do Not Donate

The Committee determined that the most appropriate term for describing an individual who intends to donate and starts the process is "potential living donor."[45] Referring to individuals who intend to become a living donor as a "candidate" could cause confusion among the community, since OPTN policy defines "candidate" as "a person registered on the organ transplant waiting list." The Committee explored various definitions for a potential living donor, including defining a potential living donor as anyone who had completed evaluation or reached the decision-making stage.[46] However, these definitions were deemed too late to capture crucial information about barriers encountered during the evaluation process. Another suggestion was to define a potential living donor as someone who completed *OPTN Policy 14.4 Medical Evaluation*, but this was found to be highly variable among transplant programs and insufficient for capturing barrier information.[47] The idea of defining a candidate as an individual who contacted a program to learn about donation was also considered but dismissed as too broad, encompassing a large population and failing to capture meaningful data due to high attrition rates at that early stage. Defining a candidate as someone who underwent evaluation and was approved was considered but deemed too late, as most proceed to surgery, missing the opportunity to analyze barriers. The Committee also considered defining a potential living donor as completing at least one part of the evaluation and being reviewed in a multidisciplinary selection committee meeting.[48]

The Committee continued to deliberate on the specific start point for data collection within the evaluation process.[49] Some options discussed were:

- First verbal contact, suggested to capture barriers early, despite potential administrative additions.
- First in-person appointment with a member of the transplant team.
- First initiation of contact with a member of the living donor team or independent living donor advocate (ILDA), whether virtual or in person. A member noted this option would better capture barriers.
- At first full evaluation as a team, suggested to reduce administrative effort since it is later in the process.
- When the first tests are ordered or the first appointment with a member of the transplant team or the ILDA. This option aligned with data collection for pre-waitlist candidates and was supported by the Data Advisory Committee (DAC).

[45] Meeting Summary for February 26, 2025, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/rewls130/20250226_livingdonorcomm_meeting-summary.pdf (accessed May 5, 2025).
[46] Meeting Summary for October 3, 2023, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/q5eh2ycp/20231003_ldc_summary_final.pdf (accessed May 5, 2025).
[47] Ibid.
[48] Meeting Summary for September 12, 2024, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/hcfeppdk/20240912_living-donor-meeting-summary.pdf (accessed May 5, 2025).
[49] Ibid.

Factors influencing the proposed start point of data collection included alignment with planned data collection triggers for pre-waitlist candidates, additional data entry responsibility on transplant centers, the need for uniformity across centers despite variations in processes, the feasibility of monitoring the start point, and capturing barriers to donation. Some members expressed concern that a later start point like the first in-person appointment might miss early psychosocial barriers.[50]

Despite these concerns, the Committee ultimately reached a consensus that the trigger for data collection on potential living donors would be the first in-person appointment with the transplant team. This decision was also supported by the SRTR and was seen as clear and manageable for centers, while providing enough data for a comparator group.

Data Collection: Living Donors and Potential Living Donors Who Do Not Donate

Long-Term Follow-Up

This proposal includes removal of the two-year OPTN required living donor follow-up. The OPTN would continue to require the current six-month and one-year OPTN submission, but voluntary follow-up would be administered by the SRTR annually after the one-year anniversary of donation. Additionally, the SRTR would contact potential living donors who did not go on to donate on an annual basis to assess long-term outcomes and collect data to compare to long-term living donor data.

Transitioning long-term follow-up (after one year) of living donors to the SRTR would shift this responsibility from transplant programs to the SRTR. The SRTR would contact individuals by phone or email, using data shared by the OPTN.[51] Follow-up after the one-year anniversary would be voluntary. The SRTR will use patient-centered approaches such as surveys administered via email or telephone. The Committee supports the OPTN's role in monitoring patient safety events during the peri-operative period and does not propose changes to required data reporting at six months or one-year post-donation. Additionally, this change would not preclude recovery hospitals from following up with living donors beyond the one-year anniversary of donation but there would be no required OPTN data submission. The Committee decided against reducing the current required reporting window of two-years for living donor patient safety events to one-year in support and prioritization of living donor safety. Recovery hospitals are encouraged to continue patient follow-up and will be expected to report any required reporting event to the OPTN if they become aware. Should the SRTR learn of any of these events, they will report the event to the OPTN and HRSA, to proceed with the standard inquiry and investigation process.

Beginning with the two-year anniversary of donation, the SRTR would follow up with living donors annually to better track long-term outcomes. Long-term follow-up aims to improve tracking of outcomes for living donors and non-donors and to analyze barriers to living donation.

Currently, there is no OPTN requirement for follow-up for collecting follow up data on living donors beyond two years. Current data on long-term outcomes for living donors are considered inadequate for

[50] Ibid.

[51] All data entered into the OPTN Computer System is shared with SRTR through a data use agreement.

accurately understanding the risks and benefits of donation.[52] As part of the Task 5 Initiative, the SRTR spent a year collecting feedback from the transplant community about transplant care, access to information, and desired changes from community members.[53] The 2022 Consensus Conference, a part of the Task 5 Initiative, included specific recommendations focused on collecting data on the long-term living donor experience.[54] Potential living donors must currently assess risk and make a donation decision based on two years of outcomes data.[55] Long-term follow-up of living donors will better aid potential living donors in assessing risk with more outcomes data.

The SRTR Living Donor Collective is specifically designed and contracted by HRSA to study the long-term health effects of living organ donation. By transitioning the follow-up responsibility, the SRTR Living Donor Collective can focus its resources on long-term follow-up activities and data linkages. The SRTR offers the capacity and expertise to perform data linkages for long-term living donor outcomes, including links to pharmacy databases and census track data which provide insight on clinical and socioeconomic outcomes.[56]

The Committee reached a consensus to remove the two-year follow-up but to retain the one-year follow-up for the OPTN.[57] The Committee reviewed the data collected at one year to ensure they are efficient and collect critical clinical information. This hybrid approach is intended to capture patient safety concerns in the peri-operative period (six-month, retained) and provide a valuable clinical check at one year before the SRTR Living Donor Collective takes over long-term follow-up. Public comment on removing the one-year and two-year requirements was mixed, with some supporting the change for reduction of administrative burden and improved data collection, while others expressed concern about shifting responsibility to donors, loss of monitoring, and potential impact on donor ease of mind regarding follow-up from their transplant center.[58] Feedback on the decision to remove the two-year follow-up is again requested for this proposal.

Existing forms for living donors, including the Living Donor Feedback, Living Donor Registration (LDR), and Living Donor Follow-Up (LDF), would still be required and collected by the OPTN. The new Living Donor Non-Donation form would also be required and collected by the OPTN, which the SRTR would then operationalize for follow up. Additionally, the Living Donor Feedback form would need to be

[52] Concepts for a Collaborative Approach to Living Donor Data Collection. OPTN Living Donor Committee, June 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/ (accessed May 5, 2025).

[53] The Scientific Registry of Transplant Recipients (SRTR) is operated under contract from the Health Resources and Services Administration (HRSA). While many tasks are required of SRTR, HRSA established "Task 5" in September 2020 with the goal to "identify metrics to assess national transplantation system performance and support informed decision-making by critical audiences.

[54] Snyder JJ, Schaffhausen CR, Hart A, Axelrod DA, Dils D, Formica Jr RN, Gaber AO, Hunt HF, Jones J, Mohan S, Patzer RE, Pinney SP, Ratner LE, Slaker D, Stewart D, Stewart Lewis Z, Van Slyck S, Kasiske BL, Hirose R, Israni AK. "Stakeholders' Perspectives on Transplant Metrics: The 2022 Scientific Registry of Transplant Recipients' Consensus Conference." Am J Transplant. 2023 Jul;23(7):875-890. doi: 10.1016/j.ajt.2023.03.012.

[55] Meeting Summary for May 14, 2025. OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/evblrmkx/20250514_livingdonorcomm_meeting-summary.pdf (accessed May 15, 2025).

[56] Meeting Summary for February 9, 2024. OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/ediij5hm/20240209_ldc_summary.pdf (accessed May 5, 2025).

[57] Meeting Summary for April 10, 2024. OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/5bkox0zf/20240410_ldc_summary.pdf (accessed May 5, 2025).

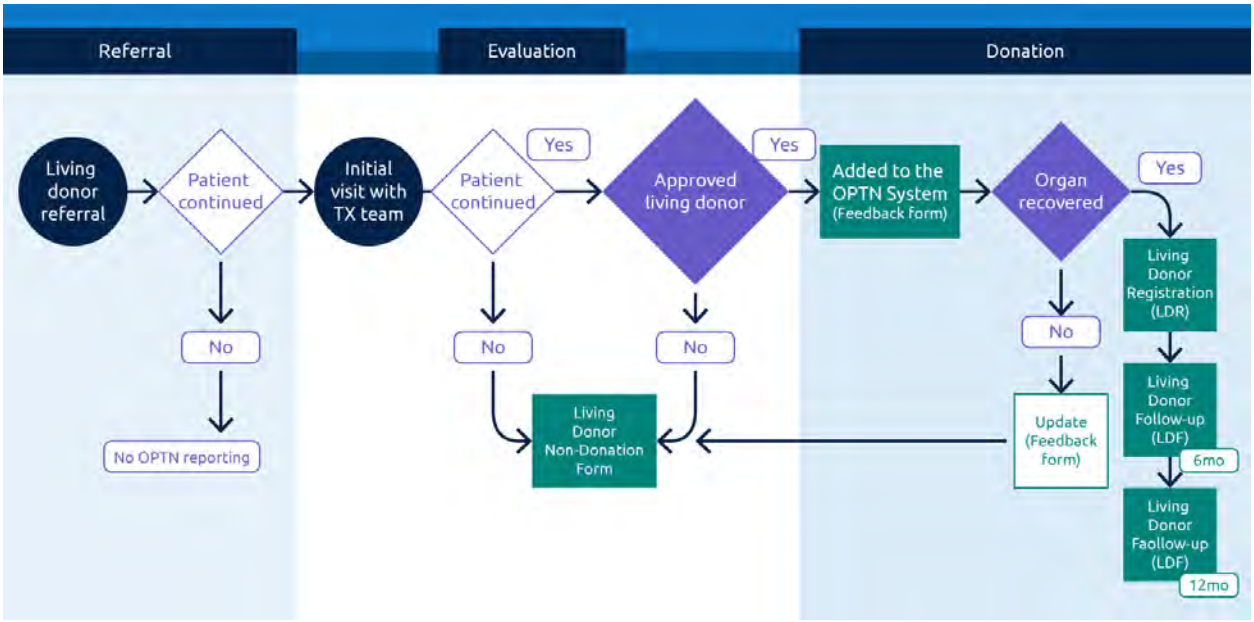
[58] Meeting Summary for October 3, 2023. OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/q5eh2ycp/20231003_ldc_summary_final.pdf (accessed May 5, 2025).

collected by recovery hospitals if a potential living donor is approved for donation but does not go on to donate. The reason for this is to create consistency in data collection across all programs and ensure that living donor feedback records are not left incomplete with no outcomes.

While the data collected from the new Living Donor Non-Donation form would require additional administrative effort, the shift of follow-up at the two-year mark would no longer be the transplant center's responsibility. The expectation for donors and potential living donors is that they will be able to complete SRTR follow up survey without contacting their transplant center. Clinical information such as laboratory results may be requested if the individual does have that information available. It is indeterminate, however, whether potential and actual donors will have clinical data available for reporting. Data collected by the SRTR will not be considered OPTN data but can be requested by the Committee for review periodically. The SRTR will have access to external data sources to complement voluntary data collection to define long-term outcomes.

Below (**Figure 3**) is a diagram depicting the proposed future state of the OPTN living donation data collection process, including required forms for living donation and potential living donors who did not donate.

Figure 3: OPTN Living Donation Collection – Proposed Future State



OPTN Data Advisory Committee Feedback on Data Collection

The OPTN Data Advisory Committee (DAC) closely reviewed the proposed new data elements to be collected on the new form, but declined to provide endorsement for the proposal.[59] The DAC requested to remove data elements to reduce the administrative responsibility of transplant centers, keeping only

[59] Meeting Summary for April 14, 2025, Data Advisory Committee, https://optn.transplant.hrsa.gov/media/pg3f5acf/20250414_dac_committee-meeting-summary-final.pdf (accessed May 5, 2025).

those data elements that are critical to the project goals of understanding the barriers to living donation and expanding knowledge about long-term outcomes of living donors. Additionally, the DAC requested the Committee determine which fields are likely discrete versus manual entry and attempt to reduce the amount of manual entry.[60] By focusing on a smaller, more manageable set of discrete data points, programs could potentially collect this information retrospectively in batch intervals, easing the administrative load.

While the DAC acknowledged that the SRTR has successfully managed a voluntary Living Donor Collective for several years, it emphasized that the proposed OPTN data collection introduces a different set of expectations for transplant programs. Specifically, the new Living Donor Non-Donation form would require timely and mandatory data submission on all potential living donor patients, potentially increasing the administrative responsibility. The DAC also suggested that the data collection effort include a question allowing potential living donors who do not proceed with donation to opt out of follow-up status monitoring after one year. This would respect patient autonomy while also helping to streamline data management.

DAC also raised broader questions about the purpose and utility of the proposed data collection and stated it remains unclear how the Living Donor Committee or SRTR plans to use the data, and what specific aims are intended to justify the effort involved. These concerns are compounded by SRTR's historical challenges in successfully collecting voluntary follow-up data on patients post-transplant, casting concern around the feasibility and long-term value of the initiative. The Committee's support for the proposed solution reflects much deliberation to come to consensus on the right option. While the Committee considers SRTR capable of being successful, community feedback is specifically requested on this item.

The Living Donor Committee data collection workgroup acted on the DAC's concern by closely reviewing and removing proposed data elements and also simplifying the response options in the new Living Donor Non-Donation form.[61,62] There was not a requested threshold for which discrete data fields must exceed manual entry, but the Committee reduced some manual fields in revision of the form. Since recovery centers do not all use the same electronic records management systems, it is difficult to standardize determination of which data elements are discrete and which are manual. Centers are encouraged to work with their software providers to adjust data collected using current elements to more easily integrate with the new Living Donor Non-Donation form.

Additionally, the Living Donor Committee emphasized that while the new Living Donor Non-Donation form listed many data elements that recovery center staff may potentially complete, only those elements with readily available information, including decision reason, would be collected on the new required form.[63] It is possible that the decision not to donate might occur after the first in-person

[60] This proportion may differ across centers depending on the system used at each recovery hospital.
[61] Meeting Summary for April 17, 2025, Living Donor Committee Decision Data Collection Workgroup, https://optn.transplant.hrsa.gov/media/loubwxvd/20250417_ld-wg-meeting-summary.pdf (accessed May 16, 2025).
[62] Meeting Summary for May 8, 2025, Living Donor Committee Decision Data Collection Workgroup, https://optn.transplant.hrsa.gov/media/t10ehnvl/20250508_ld-wg-meeting-summary.pdf (accessed May 16, 2025).
[63] Meeting Summary for May 14, 2025, Living Donor Committee, https://optn.transplant.hrsa.gov/media/evblrmkx/20250514_livingdonorcomm_meeting-summary.pdf (accessed July 1, 2025).

meeting with the transplant team, in which case only minimal data would have been collected on the potential living donor.. These results were also provided to the DAC.[64]

The Living Donor Committee also considered DAC's request to add an "opt out" option for potential living donors who do not wish to be contacted for follow-up. Committee members determined that this option is not necessary since the potential living donors can decline future follow-up at any time, since the SRTR would administer voluntary follow-up.[65] SRTR additionally reported that opt-out decisions are rare in the current Living Donor Collective registry.[66]

Changes to existing OPTN Living Donor forms

Minor changes to some data elements are proposed to the existing required forms for living donors. The intention of changes to these forms is so data collected in fields in the new Living Donor Non-Donation form can be compared to the data collected for living donors. This will allow for future comparison and analysis of longer-term outcomes, beyond two years, for living donors and potential living donors who do not donate.

A new field to capture Patient ID was added to all three existing forms, since this will be captured on the new Living Donor Non-Donation form. The reason for this is to capture a potential living donor that may proceed through the living donation process multiple times (either as living donor or potential living donor who did not donate). Data can be analyzed to see that the same patient (same Patient ID) went through the donation process on separate occasions at the same recovery center.

A comprehensive chart including each change and addition to existing forms can be found in Proposed Changes to Data Collection.

Living Donor Feedback Form: If a potential living donor undergoes anesthesia for the recovery before the donation was aborted, a surgical addendum section appears on the new Living Donor Non-Donation form. This information will allow for more focused long-term follow-up questions. Because this section is a part of the new form, the Living Donor Feedback form includes a question to determine if the surgical addendum should appear to capture this circumstance.

Living Donor Registration Form: More specific urine tests, a spot test, are proposed data collection elements in the new Living Donor Non-Donation form for kidney living donors because they are more accurate. The LDR includes changes to specify that urine protein, albumin, and creatinine be reported in a spot test. Additionally, elements to measure creatinine clearance and standardized glomerular filtration rate (GFR) in living kidney donors were added since they are also captured on the new Living Donor Non-Donation form. Field options to capture surgical information for both living kidney and liver donors were modified to match the new form options.

[64] Meeting Summary for May 12, 2025, Data Advisory Committee, https://optn.transplant.hrsa.gov/media/ptsd0n2e/20250512_dac_committee-meeting-summary-final.pdf (accessed July 1, 2025).
[65] Meeting Summary for May 14, 2025, Living Donor Committee, https://optn.transplant.hrsa.gov/media/evblrmkx/20250514_livingdonorcomm_meeting-summary.pdf (accessed July 1, 2025).
[66] Ibid.

Living Donor Follow-Up Form: More specific urine tests, a spot test, are proposed data collection elements in the new Living Donor Non-Donation form for kidney living donors because they are more accurate. The LDR and the LDF both include changes to specify that urine protein, albumin, and creatinine be reported in a spot test. Additionally, elements to measure creatinine clearance and standardized glomerular filtration rate (GFR) in living kidney donors were added since they are also captured on the new Living Donor Non-Donation form.

Changes to OPTN Data Submission Requirements

Living Donors

There are no major changes to data submission requirements for the current Living Donor Feedback, and Living Donor Registrations forms. The submission of the required Living Donor Follow-up form upon the two-year anniversary of donation is removed.

Potential Living Donors Who Do Not Donate

There will be new data submission requirements for potential living donors who meet in-person with a transplant team member but do not donate. The in-person meeting is the trigger for required data collection and submission of the Living Donor Non-Donation form.

The recovery hospital will be required to submit the Living Donor Non-Donation form 90 days after the recovery hospital has identified that the donor organ recovery procedure for a potential living donor will not proceed at their facility. While this form contains options to complete demographic, medical, clinical, surgical, and donation decision, only information that is available needs to be submitted. If a potential living donor does not go on to donate, the amount of data to input can vary depending on the point at which the donation decision occurs. The 90-day timeframe aligns with the time also required to submit both the LDR and LDF for living donors.

The recovery hospital will be required to complete the Living Donor Feedback form within 30 days after the recovery hospital has identified that the donor organ recovery procedure for a potential living donor that has been approved to donate will not proceed at their facility.

The comprehensive chart detailing the proposed data submission changes, including unchanged requirements, is found in the policy language changes Table 18-1 following this narrative.

Other policy language changes

Additional minor policy language changes are included in this proposal to better align existing language to proposed changes, remove outdated language, and provide clarity to existing policy.

A new definition was added for “potential living donor” since this population is referenced in the proposed additional reporting requirements for the new Living Donor Non-Donation form in *Table 18-1: Data Submission Requirements*. The proposed definition is “a living individual who intends to donate an organ for transplantation but from whom an organ has not yet been recovered.” Other tables in living

donor policy are modified to include the word "potential" preceding "living donor" to better clarify that the requirements must be met in advance of living donation.

The definition of recovery hospital is changed to align with the updated definition currently in OPTN Management and Membership Policies.[67,68] The new definition is changed from "a healthcare facility that recovers living donor organs" to "a transplant hospital that performs the surgery to recover living donor organs for transplantation."

The definition for "therapeutic donor" is removed since this term is outdated and unnecessary. Instead, policy refers to patient donors who have an organ removed as medical treatment as either "domino" or "non-domino" therapeutic donors.[69] There are no changes to applicable policies for these donors, but only clarification of terminology. Additional locations in policy language are adjusted to better clarify these terms. Additionally, *Table 18-1: Data Submission Requirements* clarifies that reporting requirements for the proposed Living Donor Non-Donation form does not apply to domino and non-domino therapeutic donors, since these donors must become living donors as part of medical treatment.

Language exempting reporting requirements during specific timeframes in the past for reporting requirements after living kidney donation and reporting requirements after living liver donation was removed, since it is outdated and no longer relevant.

A comprehensive section of proposed policy language changes is found below, after this narrative.

Future Steps: Phase 2

The Committee's intention is to propose minimal changes to satisfy the goals of Phase 1 of this proposal, to collect data to better understand barriers to living donation, and to allow for long-term follow-up of living donors. Future Committee work will include a comprehensive granular review of all living donor data collection instruments (required forms) and improvements and updates to the new Living Donor Non-Donation form, building upon this effort in a second phase. The two-phased approach was introduced to the transplant community in the 2023 Concept Paper and also supported by the OPTN Executive Committee.[70]

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) stated that oversight over living donation of all types falls under the authority of the OPTN.[71] In that notice, the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with [42 CFR 121.8].[72] The Committee

[67] OPTN Management and Membership Policies, Appendix M, (March 27, 2025).
[68] The OPTN Management and Membership Policies require living donor recovery hospitals to be approved transplant hospitals, not just a healthcare facility, so it was more appropriate to align the OPTN Policy definition with the OPTN Management and Membership Policy definition than vice versa.
[69] A domino therapeutic donor donates and receives a replacement organ, while a non-domino donor donates, but does not receive a replacement organ.
[70] Concepts for a Collaborative Approach to Living Donor Data Collection. OPTN Living Donor Committee, June 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/ (accessed May 5, 2025).
[71] Department of Health and Human Services, Health Resources and Services Administration, "Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines," 71 Fed. Reg. 34946 No. 116 (June 16, 2006).
[72] Ibid.

submits their proposal under the authority of this Secretarial directive; and the National Organ Transplant Act (NOTA), which requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"[73] as well as the Final Rule, which requires the OPTN to "maintain records of all transplant candidates, all organ donors and all transplant recipients."[74] Federal regulations also authorize the OPTN and SRTR to collect information concerning living organ donors and prospective living organ donors as the Secretary deems appropriate.[75]

This proposal addresses living organ donors by collecting data on individuals evaluated for living donation and updating living donor policy in an effort to determine barriers to living donation and risks and benefits attributable to living donation. This project will review OPTN living donor data collection forms and propose modifications in order to ensure accurate data collection on living donors and improve analyses to inform evidence-based policy making.

Implementation Considerations

Member and OPTN Operations

Implementation Plan

The new Living Donor Non-Donation form would be required for all potential living donors who meet in person with a transplant team member and who do not donate at any point after this meeting occurs. The start date for this requirement would be any in person meeting that occurs from the day of implementation onward. Recovery hospitals will continue to submit required existing forms for living donors, but would no longer be required to complete the two-year required follow-up for living donors whose second anniversary of recovery falls after the day of implementation.

This proposal is expected to affect the operations of transplant recovery hospitals, and the OPTN, but is not expected to affect the operations of histocompatibility laboratories or organ procurement organizations.

Operations affecting Transplant Hospitals

Only hospitals approved for a living donor component would be affected. An additional form, the Living Donor Non-Donation form, will be required to be submitted to the OPTN. Workflow changes may be required to accommodate the additional requirement, and local software systems may need to be updated to adjust to the changes in data collection fields and options.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

[73] 42 USC § 274(b)(2)(I).
[74] 42 CFR § 121.11(a)(1)(ii)
[75] 42 CFR 121.11.

Operations affecting the OPTN

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB-approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Potential Impact on Select Patient Populations

The collection of additional data on a new Living Donor Non-Donation form is intended to allow for a better understanding of the barriers to living donation. If barriers are better understood, this knowledge can lead to efforts to mitigate the barriers to transplant, to increase living donation. Collection of data on this form can also support better understanding of long-term health impacts for living donors by creating a suitable comparator group. Long-term follow-up of both living donors and potential living donors who did not donate includes voluntary request of these populations to spend time to complete follow-up via a survey administered by the SRTR.

Projected Fiscal Impact

The Fiscal Impact Advisory Group, comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

This proposal is expected to have a low-medium impact on transplant programs, depending on living donor program size. No fiscal impact was recorded for organ procurement organizations or histocompatibility labs.

Projected Impact on Histocompatibility Laboratories

There were no significant fiscal impacts indicated with this proposal.

Projected Impact on Organ Procurement Organizations

There were no significant fiscal impacts indicated with this proposal.

Projected Impact on Transplant Hospitals

There is a low-medium expected fiscal impact on transplant hospitals, dependent on the size of the living donor program. Transplant programs may need additional training and education for staff. Large living donor programs may need additional staff to complete new data collection. There may be costs to update electronic record management systems to auto-import fields.

Projected Impact on the OPTN

It is estimated that $(redacted) would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the updated policy requirements and associated system tools. In addition, implementation would include building communications and education materials, updating process documents, and community outreach. It is estimated that $(redacted) would be needed for ongoing support. Ongoing support includes member support and education, compliance monitoring, system maintenance, and answering member questions as necessary. In addition, ongoing support will include a monitoring report at the 6-month, 1-year, and 2-year timeframes. The total for implementation and ongoing support is estimated to be $(redacted).[76]

Post-implementation Monitoring

Member Compliance

An OPTN Contractor, on behalf of the OPTN, will continue to monitor all required data collection for living donor programs, which will include new required data collection for potential living donors. During site surveys of living donor recovery hospitals, the OPTN will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System are consistent with source documentation available at the time of entry, to include the addition of the Living Donor Non-Donation form and its required data elements.

Living donor recovery hospitals will no longer be required to submit 2-year post-donation follow-up forms to the OPTN. However, living donor recovery hospitals will still be responsible for submitting patient safety events within two years of donation as outlined in *OPTN Policy 18.5.B: Required Reporting of Living Donor Events by Recovery Hospitals.*

In addition to the changes to current routine monitoring of OPTN members outlined above, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

Policy Evaluation

The impact of *Update and Improve Efficiency in Living Donor Data Collection* proposal will be monitored six months post-implementation and then annually for two years, as the Committee requests. Each report will include the following as data availability allows:

- Frequency tables of all responses for reasons not to donate
- Distributions and counts comparing donors and potential living donor characteristics
    - Distributions for continuous variables
    - Counts for discrete variables
- Percent of the Living Donor Non-Donation form completed on time
    - Nationally and by region

[76] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved. Resources estimates are exempted from public disclosure under the Freedom of Information Act exemption 4.

The Living Donor Committee will review the results of the monitoring and consider whether any further changes are needed to the data fields or form completion requirements.

Conclusion

This proposal represents a critical advancement in the OPTN's efforts to improve the safety, transparency, and effectiveness of living organ donation. By expanding data collection to include individuals who do not proceed with donation and transitioning long-term follow-up responsibilities to the SRTR, the OPTN Living Donor Committee seeks to address longstanding gaps in knowledge about the full spectrum of living donation experiences.

The proposed changes will enable the transplant community to better understand the barriers to donation, assess long-term health and psychosocial outcomes, and refine policies to support donor protection and informed consent. The introduction of the Living Donor Non-Donation form and updates to existing data collection instruments will provide a more complete and accurate dataset, allowing for meaningful comparisons between donors and non-donors. This, in turn, will support evidence-based policy development and improve the equity and efficiency of the living donation process.

Through a phased and collaborative approach, this initiative lays the foundation for a more robust and responsive data infrastructure. It reflects the Committee's commitment to continuous improvement and to ensuring that living donors—and those who consider donation—are supported by the best available information and care.

Considerations for the Community

1. Living Donor Non-Donation form:
    a. Do the proposed data fields support the goals of this project?
    b. Should all data fields be mandatory or should some be optional?
2. Reporting Requirements:
    a. In this proposal, if the potential donor is approved to donate but does not donate, the recovery center has 30 days after the decision to not donate to submit the Living Donor Feedback form. Do you agree with this turnaround timeframe of 30 days?
    b. Is the 90-day turnaround an appropriate timeframe to submit the Living Donor Non-Donation form?
3. Are there any concerns related to barriers to donation or long-term outcomes not addressed among members of the living donor community?
4. Do you endorse removal of the current two-year required OPTN follow-up data collection and submission for living donors, to be changed to a voluntary annual follow-up administered by the SRTR (centers are still encouraged to follow up with patients, but no data submission would be required)? Do you endorse the SRTR contacting the patient directly?
5. Are there any educational considerations that you believe would be helpful for living donors to understand these potential changes?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

Policy 1: Administrative Rules and Definitions

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

D

[…]

Domino therapeutic donor

An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.

P

[…]

Paired donor

A potential living donor who intended to donate his organ to his paired candidate before entering into KPD.

Potential Living Donor

A living individual who intends to donate an organ for transplantation but from whom an organ has not yet been recovered.

R

[…]

Recovery hospital

~~A healthcare facility that recovers living donor organs.~~ A transplant hospital that performs the surgery to recover living donor organs for transplantation.

T

[…]

~~**Therapeutic donor**~~

~~An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.~~

14.3 Informed Consent Requirements

The living donor recovery hospital is responsible for obtaining and documenting informed consent prior to organ recovery. Informed consent requirements must include *all* of the components in *Tables 14-1* through *14-5*. Documentation of informed consent must be maintained in the living donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent:
Obtain from <u>potential</u> living donors	The living donor's signature on a document that confirms that the donor: 1. Is willing to donate 2. Is free from inducement and coercion 3. Has been informed that he or she may decline to donate at any time
Provide to <u>potential</u> living donors	1. An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential. 2. The ILDA must be available to assist the living donor during the consent process, according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* 3. Instruction about all phases of the living donation process, which includes: • Consent • Medical and psychosocial evaluations • Pre- and post-operative care • Required post-operative follow-up according to OPTN *Policy 18.4: Living Donor Data Submission Requirements.* Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital's staff.
Disclose to <u>potential</u> living donors	1. It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations. 2. The recovery hospital must provide an ILDA. 3. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation. 4. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs.

	5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment. 6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient. 7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: • Exceed local or national averages • Do not necessarily prohibit transplantation • Are not disclosed to the living donor 8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: • The reasons for a transplant candidate's increased likelihood of adverse outcomes • Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law 9. Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. 10. The recovery hospital is required to: a. Report living donor follow-up information, at the time intervals specified in OPTN *Policy 18.4: Living Donor Data Submission Requirements* b. Have the donor commit to post donation follow-up testing coordinated by the recovery hospital. c. Obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease. 11. Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care: a. May need to be reported to local, state or federal public health authorities b. Will be disclosed to their recipient's transplant hospital c. Will be reported through the OPTN Improving Patient Safety Portal 12. A living donor must undergo a medical evaluation according to OPTN *Policy 14.4: Medical Evaluation Requirements for Living Donors* and a psychosocial evaluation as required by OPTN *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. 13. The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria 14. The following are inherent risks associated with evaluation for living donation: a. Allergic reactions to contrast b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the living donor

The recovery hospital must:	These elements of informed consent :
	e. Discovery of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team 15. There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, *all* of the following: a. Potential medical or surgical risks: i. Death ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the living donor's lifestyle from donation c. Potential financial impacts: i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs ii. Need for life-long follow up at the living donor's expense iii. Loss of employment or income iv. Negative impact on the ability to obtain future employment v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

Table 14-2: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
Provide to all <u>potential</u> living kidney donors	Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include: a. On average, living donors will have a 25-35% permanent loss of kidney function after donation.
	b. Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors. c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD. d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney. e. Dialysis is required if the living donor develops ESRD. f. ~~Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to~~ <u>See OPTN</u> *Policy 8.3: Kidney Allocation Points*~~.~~ <u>for prioritization of prior living donors who become kidney candidates.</u> <u>g. See OPTN *Policy 10.1: Lung Composite Allocation* Score for prioritization of prior living donors who become lung candidates.</u>
Disclose to all <u>potential</u> living kidney donors	Surgical risks may be transient or permanent and include but are not limited to: • Decreased kidney function • Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
Disclose to all <u>potential</u> female living kidney donors	Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation

Table 14-3: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery hospital must:	These additional elements as components of informed consent for living liver donors:
Disclose to all <u>potential</u> living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. • Biliary complications, including leak or stricture that may require additional intervention. • Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.

Table 14-4: Additional Requirements for the Informed Consent of Living Donors of Covered VCAs

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:

Disclose to all <u>potential</u> living donors of covered VCAs other than covered genitourinary organ VCAs	There are surgical, psychosocial, and financial risks associated with living donation of covered non-genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, *all* of the following:
	• Potential surgical risks:
	  • Loss of function
	  • Physical disability
	  • Physical disfigurement
	• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome
	• Potential financial impacts: Procedure may not be covered by health insurance

Disclose to all potential living donors of covered genitourinary organ VCAs	There are surgical, psychosocial, and financial risks associated with living donation of covered genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, *all* of the following:
	• Potential surgical risks:
	  • Bowel injury
	  • Need for hormonal replacement therapy
	  • Pain or discomfort with intercourse
	  • Partial or complete loss of organ-specific function including reproductive function
	  • Physical disfigurement
	  • Urinary tract injury or dysfunction
	• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome
	• Potential financial impacts: Procedure may not be covered by health insurance

As part of the informed consent process, recovery hospitals must also provide transplant recipient outcome and transplanted organ survival data to potential living donors according to *Table 14-5*. The requirements in Table 14-5 do not apply to donors of covered VCAs.

14.4.A Living Donor Medical Evaluation Requirements

A medical evaluation of the potential living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-6* through *14-10* below.

Table 14-6: Requirements for ~~Living Donor~~ Medical Evaluations of Potential Living Donors to Become Living Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems

This evaluation must be completed:	Including evaluation for and assessment of this information:
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)

Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis B core antibody (total anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA)

This evaluation must be completed:	**Including evaluation for and assessment of this information:**
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.

This evaluation must be completed:	Including evaluation for and assessment of this information:
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

14.4.B Additional Requirements for the Medical Evaluation of Potential Living Kidney Donors to Become Living Kidney Donors

Table 14-7: Additional Requirements for the Medical Evaluation of Potential Living Kidney Donors to Become Living Kidney Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney - specific donor history	A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections
Kidney-specific family history	• Kidney disease • Diabetes • Hypertension • Kidney Cancer
Physical Exam	• Blood pressure taken on at least two different occasions or 24- hour or overnight blood pressure monitoring

This evaluation must be completed:	Including evaluation for and assessment of this information:
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals
Kidney-specific tests	• Urinalysis ~~or urine microscopy~~ • Urine microscopy • Urine culture if clinically indicated • ~~Measurement of urinary protein and albumin excretion~~ • Measurement of all of the following: o Urine protein, spot o Urine albumin, spot o Urine creatinine, spot • Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection • Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history • Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring: o Calcium o Oxalate o Uric acid o Citric acid o Creatinine o Sodium
Anatomic assessment	Determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant

14.4.C Additional Requirements for the Medical Evaluation of Potential Living Liver Donors to Become Living Liver Donors

Table 14-8: Additional Requirements for the Medical Evaluation Potential of Living Liver Donors to Become Living Liver Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Liver- specific family history	• Liver diseases • Bleeding or clotting disorders
General laboratory and imaging tests	• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation
Liver-specific tests	• Hepatic function panel • Ceruloplasmin in a donor with a family history of Wilson's Disease • Iron, iron binding capacity, ferritin • Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype • must develop and follow a written protocol for testing for genetic diseases • Hospitals must develop and follow a written protocol for screening for autoimmune disease • Hospitals must develop and follow a written protocol for pre-donation liver biopsy
Anatomic assessment	A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor. The evaluation must include at least all of the following: • Assessment of projected graft volume • Donor's remnant volume, • Vascular anatomy • Presence of steatosis

14.4.D Additional Requirements for the Medical Evaluation of Potential Living Donors of Covered VCAs to Become Living Donors of Covered VCAs

Table 14-9: Additional Requirements for the Medical Evaluation of Potential Living Donors of Covered VCAs to Become Living Donors of Covered VCAs

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
Transmissible disease screening	All covered VCAs	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include *all* of the following: • Toxoplasma Immunoglobulin G (IgG) antibody test
Additional specific medical history	Uterus	• Gynecological and obstetric history including prior childbirth
Additional specific tests	Uterus	• Pap smear
Additional anatomic assessment	Uterus	• Pelvic exam • A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation
Additional transmissible disease screening	Uterus	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include *all* of the following: • Bacterial Vaginosis (Gardnerella Vaginalis) • Chlamydia by nucleic acid test (NAT) • Gonorrhea by nucleic acid test (NAT) • Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test • Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA • Trichomoniasis • Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)

66 **14.4.E Living Donor Exclusion Criteria**

67 **Table 14-10: Living Donor Exclusion Criteria**

Exclusion criteria for all Potential Living Donors	Living donor recovery hospitals may exclude a potential living donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.
	
	Living donor recovery hospitals must exclude all potential living donors who meet any of the following exclusion criteria:
	• Is both less than 18 years old and mentally incapable of making an informed decision
	• HIV, unless the requirements for a variance are met, according to OPTN *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*
	• Active malignancy, or incompletely treated malignancy that either
	  o requires treatment other than surveillance or
	  o has more than minimal known risk of transmission
	• High suspicion of donor inducement, coercion, or other undue pressure
	• High suspicion of knowingly and unlawfully acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ
	• Evidence of acute symptomatic infection (until resolved)
	• Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

Additional Exclusion Criteria for Potential Living Kidney Donors	Kidney recovery hospitals must exclude all potential living donors who meet *any* of the following additional exclusion criteria:
	• Uncontrollable hypertension or history of hypertension with evidence of end organ damage
	• Type 1 diabetes
	• Type 2 diabetes where an individualized assessment of potential living donor demographics or comorbidities reveals either
	  o evidence of end organ damage or
	  o unacceptable lifetime risk of complications

Additional Exclusion Criteria for Potential Living Liver Donors	Liver recovery hospitals must exclude all potential living donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

14.6.B Placement of Non-Directed Living Donor Organs

Prior to determining the placement of a non-directed living donor organ, including non-directed organs from domino ~~donors~~ and non-domino therapeutic organ donors, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor organ is placed, the recovery hospital must document how the organ is placed and the rationale for placement.

This requirement does not apply to non-directed living kidney donors who donate a kidney through a Kidney Paired Donation (KPD) arrangement.

14.6.C Transplant Hospital Acceptance of Living Donor Organs

A transplant hospital must only accept and transplant living donor organs according to *Table 14- 12* below.

Table 14-12: Transplant Hospital Requirements for Accepting and Transplanting Living Donor Organs

If this type of living donor organ is being recovered:	Then the recovery hospital must:
Kidney	Meet the requirements according to the OPTN *Management and Membership Policy E.6: Kidney Transplant Programs that Perform Living Donor Recovery*
Liver	Meet the requirements according to the OPTN *Management and Membership Policy F.8: Liver Transplant Programs that Perform Living Donor Recovery*
Uterus	Meet the requirements according to the OPTN *Management and Membership Policy J.5: Uterus Transplant Programs That Perform Living Donor Recovery*
Other organ types, excluding kidney or Liver	Have current designated transplant program approval for that organ type

14.9 Requirements for Domino ~~Donors~~ and Non-Domino Therapeutic Donors

~~Although domino donors and non-domino therapeutic donors are considered living donors, t~~The requirements in OPTN *Policy 14: Living Donation* are limited only to Policies 14.9 A through 14.9 E below for domino ~~donors~~ and non-domino therapeutic donors.

14.9.A Informed Consent Requirements for Domino ~~Donors~~ and Non-Domino Therapeutic Donors

Recovery hospitals must obtain the donor's signature on a document that confirms that the donor:

1. Is willing to donate
2. Is free from inducement and coercion
3. Has been informed that the donor may decline to donate at any time
4. Has received information on treatment options that would not involve organ donation

Recovery hospitals must also provide *all* of the following to domino ~~donors~~ and non-domino therapeutic donors:

1. The disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient
2. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations.
3. The disclosure that health information obtained during the evaluation for donation is subject to the same regulations as all health records and could reveal conditions that must be reported to local, state, or federal public health authorities.
4. The disclosure that any new information discovered during the domino donor's or non-domino therapeutic donor's first two years of post-donation care that indicates risk of potential transmission of infectious disease or malignancy to the recipient of the domino donor's or non-domino therapeutic donor's native organ:
    a. May need to be reported to local, state, or federal public health authorities
    b. Will be disclosed to the recipient's transplant hospital
    c. Will be reported through the OPTN Improving Patient Safety Portal
5. Information on treatment options that would not involve organ donation.
6. An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

Documentation of the informed consent must be maintained in the donor medical record.

14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non- Domino Therapeutic Donors

Recovery hospitals must evaluate domino ~~donor~~ and non-domino therapeutic donors according to *all* of the following requirements:

1. Perform an assessment for risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Service (PHS) Guideline*
2. Screen the domino donor or non-domino therapeutic donor for all of the following according to OPTN *Policy 14.4: Medical Evaluation Requirements for Living Donors*, *Table 14- 6: Requirements for Living Donor Medical Evaluations*:
    a. Transmissible diseases screening
    b. Endemic transmissible diseases
    c. Cancer screening
3. Develop and comply with written protocols for the domino ~~donor~~ and non-domino therapeutic donor exclusion criteria considering incorporating as appropriate the elements of *Table 14-10: Living Donor Exclusion Criteria*
4. Register and verify the blood type of the domino ~~donor~~ or non-domino therapeutic donor according to OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting*

Documentation of the psychosocial and medical evaluation must be maintained in the donor medical record.

14.9.C Recovery of Domino ~~Donor~~ and Non-Domino Therapeutic Donor Organs

Transplant hospitals can recover domino ~~donor~~ and non-domino therapeutic donor organs if the hospital has current designated transplant program approval for that organ type.

14.9.D Acceptance of Domino ~~Donor~~ and Non-Domino Therapeutic Donor Organs

Transplant hospitals must only accept domino ~~donor~~ and non-domino therapeutic donor organs recovered at transplant hospitals that have a current designated transplant program approval for that organ type.

14.9.E Reporting and Data Submission Requirements for Domino ~~Donors~~ and Non- Domino Therapeutic Donors

Recovery hospitals must submit the living donor feedback and living donor registration (LDR) forms for ~~the~~ domino ~~donors~~ and non-domino therapeutic donors according to OPTN *Policy 18.1: Data Submission Requirements*.

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

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, or pancreas, or covered VCA transplant recipient typed by the laboratory
OPOs	*Death Notification Registration* (DNR)	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	*Monthly Donation Data Report: Reported Deaths*	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	*Potential Transplant Recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, pancreas, or covered VCA that is offered to a potential recipient

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living Donor Feedback*	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	*Living Donor Feedback*	30 days after the recovery hospital has identified that the donor organ recovery procedure for a potential living donor will not proceed at their facility	Each potential living donor who was approved to donate.
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month and 1-year, ~~and 2 year~~ anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to domino ~~donor~~ and non-domino therapeutic donor organs.
Recovery hospitals	*Living Donor Non-Donation Form*	90 days after the recovery hospital has identified that the donor organ recovery procedure for a potential living donor will not proceed at their facility	Each potential living donor who met in person with a transplant team member, but from whom an organ was not recovered This does not apply to domino and non-domino therapeutic donor organs

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death, graft failure, or planned graft removal of a uterus • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, pancreas, or covered VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, pancreas or covered VCA candidate on the waiting list or recipient transplanted by the hospital

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	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month and 1-year~~, and 2 year~~ anniversary of the donation date

18.4 Living Donor Data Submission Requirements

The follow-up period for living donors will be a minimum of one ~~two~~ year~~s~~

The OPTN will calculate follow-up rates separately, and at least annually, for the submission of the six-month~~,~~ and 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.

18.4.A Reporting Requirements after Living Kidney Donation

~~LDF forms due between March 13, 2020 and March 31, 2021 are exempt from 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~~

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living kidney donors who donate after December 31, 2014, as follows:

1. Donor status and clinical information for 80% of their living kidney donors.
2. Kidney laboratory data for at least 70% of their living kidney donors.

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

18.4.B Reporting Requirements after Living Liver Donation

~~LDF forms due between March 3, 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

#

Proposed Changes to Data Collection

Proposed Data Collection to Transplant Information Electronic Data Interchange (TEIDI®) Living Donor Forms

Table 2-1 – Proposed data collection to Living Donor Non-Donation Form

Action	Data Field Child Field		Response Option
Institution			
Add	**Donor recovery hospital**		Select hospital from drop down list
Donor Information			
Add	**Donor Last Name**		Free text
Add	**Donor First Name**		Free text
Add	**Donor Middle Initial**		Free text
Add	**Donor SSN**		Enter value
Add	**Patient ID**		Enter value
Add	**Contact Phone**		Enter value
Add	**Email**		Free text
Add	**Donor Date of Birth**		Enter value
Add	**Donor Ethnicity**		o Hispanic or Latino o Not Hispanic or Latino o Ethnicity not reported
Add	**Donor Race**		o American Indian or Alaska Native o Black or African American o White o Asian o Native Hawaiian or Other Pacific Islander o Other *current choice options for Race will remain the same *same options as existing Living Donor forms
Add	**Citizenship**		o US Citizen o Non-US Citizen/US Resident o Non-US Citizen/Non-US Resident, Traveled to US for Reason Other Than Donation o Non-US Citizen/Non-US Resident, Traveled to US for Donation
		Country of Permanent Residence	Select from drop down list Conditional child field if “Non-US Citizen/Non-US Resident” is selected

		Year of Entry into U.S.	Enter value Conditional child field if "Non-US Citizen/Non-US Resident" is selected
Add	**Donor Birth Sex**		o Male o Female
Add	**Organ Type**		o Kidney o Pancreas o Liver o Lung o VCA o Intestine
Add	**Intended Recipient**		o Directed o Non-Directed
Clinical Information			
Add	**Was clinical information collected on potential living donor?**		o Yes o No If No, system functionality skips clinical information section
Clinical Information – Medical History			
Add	**Diabetes**		o Yes o No o Not Collected
Add	**History of gestational diabetes**		o Yes o No o Not Collected
Add	**Hypertension**		o Yes o No o Not Collected
		If yes, **Pharmacological management?**	o Yes o No
Add	**Coronary Artery Disease**		o Yes o No o Not Collected
Add	**History of Malignancy**		o Yes o No o Not Collected
Clinical Information – Family History			
Add	**Family History of Kidney Disease (Kidney only)**		o Yes o No o Not Collected
Add	**Family History of Liver Disease (Liver only)**		o Yes o No o Not Collected
Clinical Information – Measurements			

Add	**Height**		Enter value
Add	**Weight**		Enter value
Add	**BMI**		Auto calculates and display only
Clinical Information – Substance/Tobacco Use			
Add	**Alcohol consumption (drinks per week)**		o Zero o 1-7 o 8-14 o Greater than 14 o Not Collected
Add	**Nicotine/tobacco Use**		o Yes • Current • Past o No o Not Collected
Add	**Cannabis Use**		o Yes • Current • Past o No o Not Collected
Clinical Information – Labs			
Add	<u>All organs:</u> **eGFR** **Hemoglobin** **White Blood Cell Count** **Platelet Count** **HgA1c**		Enter value for each
Add	<u>Kidney Only:</u> **Serum Creatinine** **Creatinine Clearance/Raw Measured GFR** **Standardized GFR (calculated and view only)** **Urine Protein, spot** **Urine Albumin, spot** **Urine Creatinine, spot**		Enter value for each
Add	<u>Liver only:</u> **Total Bilirubin** **SGOT/AST** **SGPT/ALT** **Alkaline Phosphatase** **Serum Albumin** **INR**		Enter value for each
Clinical Information – Biopsy/Imaging (liver only)			
Add	**Was a liver biopsy performed?**		o Yes o No o Not Collected
	If Yes:	**% Macro vesicular steatosis**	Enter value

		% Micro vesicular steatosis		Enter value
		Estimated fibrosis stage		o 0 o 1 o Greater than or equal to 2
	If No:	**Was liver imaging performed?**		o Yes o No
		If Yes:	**Steatosis quantification %, as determined by your center**	o 0-10% o 11-20% o 21-30% o 31-40% o 41-50% o Over 50%
			Estimated fibrosis stage	o 0 o 1 o Greater than or equal to 2

Decision Information			
Add	**Decision Date**		Enter date
Add	**Select the reason(s) for not proceeding with donation:** Multiselect		o Medical/Surgical contraindication o Psychosocial contraindication o Donor Choice or transfer o Another Donor Selected o Recipient Related Factors
		Medical/Surgical contraindication	o Obesity o Age of donor o Diabetes/Prediabetes o Malignancy • Skin • CNS Tumor • Genitourinary • Gastrointestinal • Breast • Thyroid • Tongue/Throat • Larynx • Lung (include bronchial) • Leukemia/Lymphoma o Neurologic abnormalities o Cardiovascular abnormalities o Hypertension o Pulmonary abnormalities o Renal Insufficiency o Kidney Stones

		Multiselect	o Hepatic abnormalities o Gastrointestinal abnormalities o Contraindicated Medications o Genetic Disorders or family history o Infection transmission risk o Immunological incompatibility o Hematologic abnormalities o Anatomic or Vascular o Surgical history o Other, specify (free text)
		Psychosocial contraindication Multiselect	o Unable to provide informed consent o Unable to comply with follow-up o Unable to overcome geographical barriers o Substance use o Psychiatric Illness or family history o Concern for coercion or financial exchange o Member(s) of the family against the candidate donating o Inadequate caregiver support o Candidate reluctancy or ambivalence as indicated by missed appointments, failure to return calls, etc o Lack of heath insurance coverage o Limitations related to out-of-pocket costs o Undocumented or International Donor o Other, specify: (free text)
		Donor Choice or Transfer Multiselect	o Donor transferred to another center for donation o Limitations related to out-of-pocket costs o Difficulty taking time off work o Risk too high for health or well being o Decided against donation for undisclosed reasons o Donor declined paired exchange o Other, specify:
		Another Donor Selected	o Another living donor was a better choice for medical reasons o Another living donor was a better match (ABO or HLA) o Another living donor was a better choice for psychosocial reasons

		Multiselect	o Another living donor was chosen prior to completion of evaluation o Another living donor was a better choice for other reasons
		Recipient Related Factor Multiselect	o Intended recipient underwent deceased donor transplant o Intended recipient decided not to have this potential living donor donate o Intended recipient became too ill for transplant or died o Intended recipient organ function improved o Intended recipient evaluation delay prevented donation o Intended recipient required additional organ o Intended recipient no longer a candidate for other reasons
Surgical Addendum (only populates if certain questions on Living Donor Feedback Form answered)			
Intended Liver Surgical Information			
Add	**Intended Type of Transplant Graft**		o Left Lateral Segment o Left Lobe without MHV (Middle Hepatic Vein) o Left Lobe with MHV o Right Lobe without MHV o Right Lobe with MHV
Add	**Intended Procedure Type**		o Open o Pure Laparoscopic* o Hand-assisted Laparoscopic o Laparoscopic-assisted Open o Pure Robotic o Robotic-assisted Open
		Conversion from Laparoscopic to Open: (conditional for Pure Laparoscopic choice option)	o Yes o No
Intended Kidney Surgical Information			
Add	**Intended Type of Transplant Graft**		o Left Kidney o Right Kidney o En-Bloc o Dual Kidney o Hemi-Renal
Add	**Intended Procedure Type**		o Transabdominal o Flank (retroperitoneal) o Laparoscopic Not Hand-assisted*

			o Laparoscopic Hand-assisted* o Natural Orifice o Robotic
		Conversion from Laparoscopic to Open: (conditional for Laparoscopic choice options)	o Yes o No
Intended Lung Surgical Information			
Add	**Intended Type of Transplant Graft:**		o Lobe, Right o Lobe, Left
Add	**Intended Procedure Type**		o Open o Video Assisted Thoracoscopic
		Conversion from Thoracoscopic to Open: (conditional)	o Yes o No
Add	**Intra-operative Complications**		o Yes • Sacrifice of Second Lobe Specify (RML, RUL, LUL, Lingular) • Anesthetic Complication Specify (free text) • Arrhythmia Requiring Therapy (Medical therapy, cardioversion) • Cerebrovascular Accident • Phrenic Nerve Injury • Brachial Plexus Injury • Breast Implant Rupture • Other Specify (free text) o No
Intended Uterus Surgical Information			
Add	**Intended procedure type**		o Robotic* o Hybrid o Open
		Was there a conversion from Robotic to Open? (conditional)	o Yes o No
Add	**Operative time (surgical time from skin to skin)**	Start date and time	Enter value
		End date and time	Enter value
Add	**Ovaries removed?**		o Yes o No o Not Applicable
Add	Intra-operative complications		o Yes • Ureter Injury

		• Type of ureter injury: Unilateral, Bilateral, Other • Was injury corrected? Y/N • Anesthetic complication, specify (free text) • Other, specify (free text) o No
Intended VCA Surgical Information		
Add	**Inter-operative complications**	o Yes • Anesthetic complication, specify (free text) • Other, specify (free text) o No

Table 2-2 – Proposed data changes to Living Donor Feedback Form

Action	Field Name	Response Option	Functionality
Remove	**Living donor recovery procedure aborted after donor received anesthesia OR living donor organ recovered, but not transplanted?**	Yes	
		No	
		Not applicable	
Add	**Was the living donor organ recovered at this recovery facility?**	Yes	Opens form A2 (same as current donation workflow)
		No	Generates child question*
			Functionality: this will close out donor ID on Form A1 and open Form B to get more detail of reasons of not donating
	***Did the potential living donor undergo anesthesia for the recovery before**	Yes	Form B generates **with** "Surgical Addendum" section

		the donation was aborted? (aborted procedures must also be reported via the OPTN Improving Patient Safety Portal within 72 hours)	No	Form B generates **without** "Surgical Addendum" section

Table 2-3 – Proposed data changes to Living Donor Registration Form

Action	Field Name		Response Option
Donor Information			
Add	**Patient ID**		Enter value
Pre-Donation Liver Clinical Information			
Modify	% Macro intermediate vesicular fat	**% Maco vesicular steatosis**	Enter value
Modify	% Micro intermediate vesicular fat	**% Micro vesicular steatosis**	Enter value
Kidney Clinical Information			
Modify	Urinalysis	**Urine Tests**	Label only, no response option
Add		**Urine protein, spot**	Enter value
Add		**Urine albumin, spot**	Enter value
Add		**Urine creatinine, spot**	Enter value
Add		**Creatinine clearance/raw measured GFR**	Enter value
Add		**Standardized GFR**	calculated and view only
Remove	Protein Creatinine Ratio		
Remove	Urine Protein		
Liver Surgical Information			
Add	**Intended Procedure Type**		Open Pure Laparoscopic* Hand-assisted Laparoscopic Laparoscopic-assisted Open Pure Robotic Robotic-assisted Open
		Conversion from Laparoscopic to Open: (conditional)	Yes No

Table 2-4 – Proposed data changes to Living Donor Follow-up Form

Action	Field Name		Response Option
Donor Information			
Add	**Patient ID**		Enter value
Kidney Clinical Information			
Modify	Urinalysis	**Urine Tests**	Label only, no response option
Add		**Urine protein, spot**	Enter value
Add		**Urine albumin, spot**	Enter value
Add		**Urine creatinine, spot**	Enter value
Add		**Creatinine clearance/raw measured GFR**	Enter value
Add		**Standardized GFR**	calculated and view only
Remove	Protein Creatinine Ratio		
Remove	Urine Protein		

Proposed New Data Definitions

The following table includes data definitions for the new Living Donor Non-Donation Form.

Living Donor Non-Donation Form (NDF) Data Definitions

Institution	
Donor Recovery Hospital	The Donor Recovery Hospital will be displayed. Verify this is the facility where the potential living donor evaluation occurred.
Donor Information	
Donor Last Name	Enter the potential living donor's last name. This is a **required** field.
Donor First Name	Enter the potential living donor's first name. This is a **required** field.
Donor Middle Initial	Enter the potential living donor's middle initial, if applicable.
Donor SSN	Enter the potential living donor's social security number (SSN) using the 9-digit numeric format of ######### or ###-##-####. Select **Unknown** if the potential living donor did not disclose a social security number or if the SSN is not known. Select **Not Applicable** if the potential living donor does not have a SSN. This is a **required** field.
Patient ID	Enter the potential living donor's patient ID. This is a hospital-owned patient ID that the recovery center would enter; it is unique to the program and hospital (e.g., Medical Record Number (MRN)). This is a **required** field.
Contact Phone	Enter the potential living donor's home phone number. This field is **required**.
Email	Enter the potential living donor's e-mail address. If the patient did not provide or disclose their email address, select **Email not provided**. This is a **required** field.
Donor Date of Birth	Enter the potential living donor's date of birth using the 8-digit numeric format of MM/DD/YYYY. This is a **required** field.
Donor ethnicity	The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) Statistical Policy Directive No. 15) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of ethnicity is aligned to this standard. OMB defines ethnicity to be whether a person self-identifies as Hispanic origin or not. For this reason, ethnicity is broken out in two categories, (1) Hispanic or Latino or (2) Not Hispanic or Latino. Select one ethnicity category or select Ethnicity not reported if the candidate did not self-identify. This field is **required**. • **Hispanic or Latino** – A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. • **Not Hispanic or Latino** • **Ethnicity not reported**

Donor Race	The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) Statistical Policy Directive No. 15) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of race is aligned to this standard. OMB defines race as a person's self-identification with one or more social groups. An individual can select one or more race categories (1) White, (2) Black or African American, (3) Asian, (4) American Indian or Alaska Native, (5) Native Hawaiian or Other Pacific Islander. Select Race not reported if the candidate's race is not reported. This field is **required**. Note: A person may report multiple races. Persons reporting Hispanic or Latino ethnicity may report themselves as any race category or report no race at all. Select one or more race sub-categories or origins. Select Other origin if origin is not listed. Select Origin not reported if the origin was not self-identified by the person. • White – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. o **European descent** o **Arab or Middle Eastern** o **North African (non-Black)** o **Other Origin** o **Origin not reported** • Black or African American – A person having origins in any of the Black racial groups of Africa. o **African American** o **African (Continental)** o **West Indian** o **Haitian** o **Other origin** o **Origin not reported** • American Indian or Alaska Native – A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment. o **American Indian** o **Eskimo** o **Aleutian** o **Alaska Indian** o **Other origin** o **Origin not reported** • Asian – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. o **Asian Indian/Indian sub-continent**

	○ **Chinese** ○ **Filipino** ○ **Japanese** ○ **Korean** ○ **Vietnamese** ○ **Other origin** ○ **Origin not reported** • Native Hawaiian or Other Pacific Islander – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. ○ **Native Hawaiian** ○ **Guamanian or Chamorro** ○ **Samoan** ○ **Other origin** ○ **Origin not reported** • **Race not reported** – Select if person did not self-identify a race category or origin.
Citizenship	Select as appropriate to indicate the donor's citizenship. This field is **required**. • **U.S. Citizen:** A United States citizen by birth or naturalization. • **Non-U.S. Citizen/U.S. Resident:** A non-citizen of the United States for whom the United States is the primary place of residence. • **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Reason Other Than Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for a reason other than transplant. • **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for the purpose of transplant.
Country of permanent residence	The country where the donor's primary place of residence is located.
Year of entry into U.S.	If the donor is a Non-U.S. Citizen/Non-U.S. Resident, enter the year the donor entered the United States. This field is **required**.
Donor birth sex	Report donor sex (Male or Female), based on biologic and physiologic traits at birth. If sex at birth is unknown, report sex at time of donation as reported by donor or documented in medical record. The intent of this data collection field is to capture physiologic characteristics that may have an impact on recipient size matching or graft outcome. This field is **required**.
Organ Type	Select the type of organ that was transplanted from the list. This is a **required** field. • **Kidney** • **Pancreas** • **Liver** • **Lung** • **VCA**

	• **Intestine**
Intended Recipient	Select the type of intended recipient from the list. This refers to the individual to whom the potential living donor originally wishes to donate. This is a **required** field. • **Directed** • **Non-Directed**
Clinical Information	
Was clinical information collected on potential living donor?	Select **Yes** if clinical information was collected on the potential living donor candidate during the living donor evaluation. If not, select **No**. Selecting Yes will populate additional data fields that include Medical History, Family History, Measurements, Substance/Tobacco Use, Labs, and Biopsy/Imaging (liver only). This is a **required** field.
Medical History	
Diabetes	If the potential living donor has a current or past diagnosis of diabetes, Type I or Type II, at the time of evaluation, select **Yes**. If not, select **No**. This field is **required**.
History of gestational diabetes?	If the potential living donor was ever diagnosed with gestational diabetes, select **Yes**. If not, select **No**. This field is **required**.
Hypertension	Indicate whether the potential living donor has been diagnosed with hypertension. Select **Yes** or **No**. This field is **required**. • **Yes**: If the potential living donor has hypertension, specify whether the patient is on pharmacological management for treatment. o **Pharmacological management**: Yes or No
Coronary artery disease	Indicate whether the potential living donor has a history of coronary artery disease (CAD). CAD may include documented history of coronary artery stenosis, coronary artery bypass surgery (CABG), percutaneous coronary intervention (PCI), or myocardial infarction. Select **Yes** or **No**. This field is **required**.
History of Malignancy	Indicate whether the potential living donor had a history of malignancy prior to the donation. This includes any type of malignancy, whether currently active or in remission. Select **Yes** or **No**. This field is **required**.
Family History	
Family History of Kidney Disease (Kidney only)	Indicate whether the potential living donor has a family history of kidney disease. This includes any known instances of kidney disease among the donor's first-degree biological relatives. Kidney disease refers to conditions that impair the function of the kidneys, including chronic kidney disease, polycystic kidney disease, glomerulonephritis, and other hereditary or acquired kidney disorders. Select **Yes** or **No**. This field is **required**.
Family History of Liver Disease (Liver only)	Indicate whether the potential living donor has a family history of liver disease. This includes any known instances of liver disease among the donor's first-degree biological relatives. Liver disease refers to conditions that impair the function of the liver, including but not limited to cirrhosis,

	hepatitis, fatty liver disease, liver cancer, and other hereditary or acquired liver disorders. Select **Yes** or **No**. This field is **required**.
Measurements	
Height	Enter the height of the potential living donor during evaluation in the appropriate space, in feet and inches or centimeters. If the living donor's height is not available, select the appropriate (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**. Note: Use the most recent value for height/weight when/if multiple measurements are taken.
Weight	Enter the weight of the potential living donor during evaluation in the appropriate space, in pounds or kilograms. If the living donor's weight is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**. Note: Use the most recent value for height/weight when/if multiple measurements are taken.
BMI	The potential living donor's Body Mass Index (BMI) will display.
Substance/Tobacco Use	
Alcohol consumption (drinks per week)	Indicate the potential living donor's average weekly alcohol consumption. This includes the total number of alcoholic drinks consumed per week. The options for this field are categorized as follows: • **Zero**: The donor does not consume any alcoholic drinks. • **1-7**: The donor consumes between 1 and 7 alcoholic drinks per week. • **8-14**: The donor consumes between 8 and 14 alcoholic drinks per week. • **Greater than 14**: The donor consumes more than 14 alcoholic drinks per week. This field is **required**.
Nicotine/tobacco Use	Indicate whether the potential living donor has a history of nicotine or tobacco use. Examples include cigarettes, cigars, e-cigarettes, vape, chewing tobacco, other forms of oral tobacco and other forms of nicotine like nicotine patches or gum. This field should be completed as follows: • **Y (Yes)**: The donor has a history of nicotine or tobacco use. o **Current or Past**: Specify whether the use is current or past. • **N (No)**: The donor does not have a history of nicotine or tobacco use. Note: if potential living donor used nicotine/tobacco once or sparsely, select No. This field is **required**.
Cannabis Use	Indicate whether the potential living donor has a history of cannabis use. This field should be completed as follows: • **Y (Yes)**: The donor has a history of cannabis use. • **N (No)**: The donor does not have a history of cannabis use. Note: if potential living donor used cannabis once or sparsely, select No. This field is **required**.

Labs	
All forms:	
eGFR	Enter the most recent result for estimated glomerular filtration rate (eGFR) in milliliters per minute per 1.73 square meters (mL/min/1.73 m^2). Acceptable estimation methods include creatinine-based, cystatin-based, creatinine + cystatin based eGFR. If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Hemoglobin	Enter the most recent result for hemoglobin in grams per deciliter (g/dL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
White Blood Cell Count	Enter the most recent result for white blood cell count in thousands per microliter (K/µL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required.**
Platelet Count	Enter the most recent result for platelet count in thousands per microliter (K/µL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
HbA1c	Enter the most recent result for Hemoglobin A1c (HbA1c) in percentage (%). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required.**
Kidney Only:	
Serum Creatinine	Enter the most recent result for serum creatinine in mg/dl. If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Creatinine Clearance/Raw Measured GFR	Enter the most recent result for creatinine clearance or raw measured glomerular filtration rate (GFR) in milliliters per minute (ml/min). This includes all types of measured GFR, such as 24-hour urine collection, single-sample clearance tests, or nuclear medicine scans. If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Standardized GFR (calculated and view only)	The Standardized GFR will display. Standardized GFR is calculated from the potential living donor's height, weight, and serum creatinine levels.
Urine Protein, spot	Enter the most recent result for urine protein concentration from a spot (single) urine sample, measured in milligrams per deciliter (mg/dL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required.**
Urine Albumin, spot	Enter the most recent result for urine albumin concentration from a spot (single) urine sample, measured in milligrams per deciliter (mg/dL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required.**
Urine Creatinine, spot	Enter the most recent result for urine creatinine concentration from a spot (single) urine sample, measured in milligrams per deciliter (mg/dL). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.

Liver only:	
Total Bilirubin	Enter the most recent lab value prior to donation for total serum bilirubin in mg/dL. If any of the data values are unavailable, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
SGOT/AST	Enter the most recent lab value prior to donation for the serum glutamic oxaloacetic transaminase or aspartate transaminase in U/L. If any of the data values are unavailable, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
SGPT/ALT	Enter the most recent lab value prior to donation for the Serum Glutamic Pyruvic Transaminase/Alanine Aminotransferase in U/L. If any of the data values are unavailable, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Alkaline Phosphatase	Enter the most recent lab value prior to donation for the serum alkaline phosphatase value in units/L. If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Serum Albumin	Enter the most recent lab value prior to donation for the serum albumin value in g/dL. If any of the data values are unavailable, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
INR	International Normalized Ratio. Enter the most recent prior to donation ratio of the prothrombin time (in seconds) to the control prothrombin time (in seconds). If the value is not available, select the reason from the status (ST) drop-down list (Missing, Unknown, N/A, Not done). This field is **required**.
Biopsy/Imaging *(liver only)*	
Was a liver biopsy performed?	Indicate whether a liver biopsy was performed. This field should be completed as follows: • **Y (Yes):** A liver biopsy was performed. Complete the following: o **% Macro vesicular steatosis** o **% Micro vesicular steatosis** o **Estimated fibrosis stage** • **N (No):** A liver biopsy was not performed. This field is **required**.
Was liver imaging performed? **(only populates if liver biopsy question is No)**	Indicate whether liver imaging was performed. Imaging includes ultrasound, CT, and MRI. This field should be completed as follows: • **Y (Yes):** Liver imaging was performed. Complete the following: o **Fat quantification %** o **Estimated fibrosis stage** • **N (No):** Liver imaging was not performed.
% Macro vesicular steatosis	Enter the percentage of macro vesicular steatosis. If the value is not available, select the reason from the status (**ST**) drop-down list (**Missing**, **Unknown**, **N/A**, **Not done**). (List of Status codes)

	Macrovesicular type - Large fat droplets balloon the liver cell, displacing the nucleus to the periphery of the cell, like an adipocyte. Triglyceride accumulates most commonly because it has the highest turnover rate of all hepatic fatty acid esters. Liver uptake of FFA from adipose tissue and the diet is unrestrained, whereas FFA disposition by oxidation, esterification, and VLDL secretion is limited.
% Micro vesicular steatosis	Enter the percentage of micro vesicular steatosis. If the value is not available, select the reason from the status (**ST**) drop-down list (**Missing**, **Unknown**, **N/A**, **Not done**). (List of Status codes) Microvesicular - Fatty liver, small fat droplets accumulate, cells appear foamy, and nuclei are central. Triglycerides collect in subcellular organelles (i.e., endoplasmic reticulum), reflecting widespread metabolic disturbance. Mitochondrial injury limits FFA oxidation, while apoprotein synthesis necessary for VLDL secretion is depressed, leading to triglyceride accumulation.
Steatosis quantification %, as determined by your center	Enter the percentage of steatosis quantification in the liver, as determined by your center's imaging or diagnostic methods (MRI, CT, or ultrasound). This value represents the proportion of the liver composed of fat. Select the appropriate percentage from the following drop-down options: o **0-10%** o **11-20%** o **21-30%** o **31-40%** o **41-50%** o **Over 50%** If the value is not available, select the reason from the status (**ST**) drop-down list (**Missing, Unknown, N/A, Not done**).
Estimated fibrosis stage	Enter the estimated stage of liver fibrosis, as determined by your center's diagnostic methods. Liver fibrosis refers to the scarring process that occurs in response to liver injury, and its stage indicates the extent of scarring. Select the appropriate stage from the following drop-down options: o **0**: No fibrosis o **1**: Mild fibrosis o **Greater than or equal to 2**: Significant fibrosis or cirrhosis If the value is not available, select the reason from the status (**ST**) drop-down list (**Missing, Unknown, N/A, Not done**).
Decision Information	
Decision Date	Enter the date in month/day/year (MM/DD/YYYY) format when the decision was made that the potential living donor would not proceed with donation. This date could reflect either the date the center was notified of the donor's decision to not donate or the date the center determined the donor was not eligible for donation. This field is **required**.

Select the reason(s) for not proceeding with donation:*	Indicate the best reason(s) why the potential living donor did not proceed with the donation. Select one or more of the following options: • **Medical/Surgical Contraindication**: The potential living donor was found to have medical or surgical conditions that contraindicate donation. This includes any health issues or surgical risks identified during the evaluation process that make donation unsafe for the donor or recipient. • **Psychosocial Contraindication**: The potential living donor was found to have psychosocial factors that contraindicate donation. This includes concerns related to mental health, social support, or other psychosocial issues that may impact the donor's ability to proceed with donation. • **Donor Choice or Transfer**: The potential living donor chose not to proceed with the donation, or the donor was transferred to another center for donation. This includes personal decisions made by the donor or logistical reasons for transferring the donor to a different facility. • **Another Donor Selected**: Another living donor was chosen instead of the potential donor. This could be due to medical, psychosocial, or compatibility reasons that made another donor a better choice. • **Recipient Related Factors**: The intended recipient's circumstances changed, leading to the decision not to proceed with the donation. This includes situations where the recipient underwent a deceased donor transplant, became too ill for transplant, or other recipient-related factors. This field is **required**.
<u>Medical/Surgical contraindication</u>	Select one or more of the following options:
Obesity	The potential living donor has a current Body Mass Index (BMI) greater than 30 kg/m² and is unable to donate.
Age of donor	The potential living donor's age is considered a contraindication due to increased risks associated with either very young or advanced age.
Diabetes/Prediabetes	The potential living donor has a diagnosis of diabetes or prediabetes and is unable to donate.
Malignancy	The potential living donor has a history of malignancy and is unable to donate. This includes any type of malignancy, whether currently active or in remission. • If selected, indicate the type(s) of cancer from the list provided (Multiple selections are allowed). o **Skin** o **CNS** o **Genitourinary** o **Gastrointestinal** o **Breast** o **Thyroid** o **Tongue/Throat**

	o **Larynx** o **Lung (include bronchial)** o **Leukemia/Lymphoma**
Neurologic abnormalities	The potential living donor has neurologic conditions that may impact their ability to safely undergo donation. This includes disorders such as epilepsy, stroke, or other neurologic impairments.
Cardiovascular abnormalities	The potential living donor has cardiovascular conditions that contraindicate donation. This includes coronary artery disease, heart failure, arrhythmias, or other heart-related issues.
Hypertension	The potential living donor has a history of high blood pressure and is unable to donate.
Pulmonary abnormalities	The potential living donor has lung-related conditions that contraindicate donation. This includes chronic obstructive pulmonary disease (COPD), asthma, or other pulmonary issues.
Renal Insufficiency	The potential living donor has impaired kidney function or chronic kidney disease and is unable to donate.
Kidney Stones	The potential living donor has a history of kidney stones and is unable to donate.
Hepatic abnormalities	The potential living donor has liver-related conditions that contraindicate donation. This includes cirrhosis, hepatitis, or other liver diseases.
Gastrointestinal abnormalities	The potential living donor has gastrointestinal conditions that contraindicate donation. This includes disorders such as inflammatory bowel disease, ulcers, or other gastrointestinal issues.
Contraindicated Medications	The potential living donor is taking medications that contraindicate donation. This includes nephrotoxic medications, chronic narcotics, or other drugs that may impact the donor's health and the success of the transplant.
Genetic Disorders or family history	The potential living donor has genetic disorders or a family history of conditions that contraindicate donation. This includes hereditary diseases that may pose risks for the donor or recipient. Additionally, familial or genetic cancers are considered that make a donor high risk. The strength of the family gene and the age of the donor are important factors in assessing the risk.
Infection transmission risk	The potential living donor has infections that pose a risk of transmission to the recipient. This includes active infections or a history of infectious diseases.
Immunological incompatibility	The potential living donor has immunological factors that contraindicate donation. This includes incompatibility with the recipient's immune system. This could include a situation where the recovery facility does not offer paired exchange donation. If the patient does not want to donate to paired exchange in addition to the immunological incompatibility, please also select “Donor declined paired exchange” in the “Donor Choice or Transfer” section.
Hematologic abnormalities	The potential living donor has blood-related conditions that contraindicate donation. This includes disorders such as anemia, clotting disorders, or other hematologic issues.
Anatomic or Vascular	The potential living donor has anatomical or vascular variations that contraindicate donation. This includes size/volume mismatch, anatomic

	defects, vascular anatomy or other structural differences that may impact the surgical procedure or the success of the transplant.
Surgical history	The potential living donor has a surgical history that contraindicates donation. This includes individuals who have had extensive surgical procedures that would rule them out as living donors or those who have experienced complications from previous surgeries.
Other, specify (free text)	Any other medical or surgical contraindications not listed above. Specify the reason in the free text field.
Psychosocial contraindication	Select one or more of the following options:
Unable to provide informed consent	The potential living donor is unable to understand and voluntarily agree to the donation process and its associated risks and benefits, due to cognitive impairment, language barriers, or other factors affecting their decision-making capacity.
Unable to comply with follow-up	The potential living donor is unable to commit to the necessary post-donation follow-up care and appointments which are essential for monitoring their health and ensuring a successful recovery.
Unable to overcome geographical barriers	The potential living donor faces significant challenges related to travel distance, transportation, or relocation that prevent them from participating in the donation process or follow-up care.
Substance use	The potential living donor has a history of substance abuse or dependence (e.g., alcohol, drugs) that may impact their ability to safely undergo the donation process and adhere to post-donation care.
Psychiatric Illness or family history	The potential living donor has a current or past diagnosis of psychiatric illness, or a family history of psychiatric disorders, that may affect their mental health and ability to proceed with donation.
Concern for coercion or financial exchange	There are concerns that the potential living donor may be under pressure or coercion to donate, or that there may be financial incentives or exchanges involved in their decision to donate.
Member(s) of the family against the candidate donating	One or more family members of the potential living donor are opposed to the donation, which may create emotional or social conflicts that impact the donor's decision.
Inadequate caregiver support	The potential living donor lacks a qualified caregiver to assist them during the donation process and recovery period.
Candidate reluctancy or ambivalence as indicated by missed appointments, failure to return calls, etc	The potential living donor shows signs of hesitation or uncertainty about proceeding with the donation, as evidenced by missed appointments, failure to respond to communications, or other indicators of ambivalence.
Lack of health insurance coverage	The potential living donor does not have adequate health insurance coverage to support the costs associated with the donation process and post-donation care.
Limitations related to out-of-pocket costs	The potential living donor faces financial constraints related to out-of-pocket expenses for the donation process, such as travel, lodging, and medical costs not covered by insurance or Living Donor Financial Assistance Programs.

Undocumented or International Donor	The potential living donor is an undocumented immigrant or an international donor, which may present legal, logistical, or financial challenges that impact their ability to proceed with the donation.
Other, specify: (free text)	Any other psychosocial contraindications not listed above. Specify the reason in the free text field.
Donor Choice or Transfer	Select one or more of the following options:
Donor transferred to another center for donation	The potential living donor was moved to a different medical facility for the donation process. This could be due to logistical reasons, the donor's preference, or the receiving center's capabilities.
Limitations related to out-of-pocket costs	The potential living donor's perception of out-of-pocket costs was a barrier to proceeding with the donation. This includes financial constraints related to expenses that are not covered by insurance, such as travel, lodging, and other personal costs associated with the donation process.
Difficulty taking time off work	The potential living donor encountered challenges in obtaining sufficient leave from their employment to participate in the donation process and recovery period.
Risk too high for health or well being	The potential living donor decided against donation due to concerns about the potential risks to their own health or well-being, as assessed by themselves (example: fear of surgery).
Decided against donation for undisclosed reasons	The potential living donor chose not to proceed with the donation, but did not provide specific reasons for their decision.
Donor declined paired exchange	The potential living donor was not a match for the intended recipient, but did not want to donate in a paired exchange.
Other, specify:	Any other reasons for the donor's choice or transfer that are not listed above. Specify the reason in the free text field.
Another Donor Selected	Select one or more of the following options:
Another living donor was a better choice for medical reasons	A different living donor was chosen because they were deemed to be a better medical match for the recipient. This could include factors such as overall health, organ compatibility, or lower risk of complications.
Another living donor was a better match (ABO or HLA)	A different living donor was selected because they had a better blood type (ABO) or human leukocyte antigen (HLA) match with the recipient. These factors are crucial for reducing the risk of organ rejection and improving transplant outcomes.
Another living donor was a better choice for psychosocial reasons	A different living donor was chosen due to psychosocial factors that made them a more suitable candidate. This could include better social support, mental health stability, or fewer concerns about coercion or financial incentives.
Another living donor was chosen prior to completion of evaluation	A different living donor was chosen for the intended recipient before the completion of this potential living donor’s evaluation.
Another living donor was a better choice for other reasons	A different living donor was selected for reasons not specified in the other categories. This could include logistical considerations, personal preferences, or other unique factors that made the alternative donor a better choice.

Recipient Related Factor	Select one or more of the following options:
Intended recipient underwent deceased donor transplant	The intended recipient received an organ from a deceased donor, making the potential living donor's organ no longer needed for the transplant.
Intended recipient decided not to have this potential living donor donate	The intended recipient chose not to proceed with the transplant using the potential living donor's organ. This decision could be based on personal preferences, medical advice, or other considerations.
Intended recipient became too ill for transplant or died	The intended recipient's health deteriorated to the point where they were no longer eligible for a transplant, or they passed away before the transplant could take place.
Intended recipient organ function improved	The intended recipient's organ function improved significantly, reducing or eliminating the need for a transplant from the potential living donor. This improvement could be due to medical treatment, lifestyle changes, or natural recovery, making the transplant unnecessary.
Intended recipient evaluation delay prevented donation	There was a delay in the intended recipient's evaluation that prevented donation with this potential living donor.
Intended recipient required additional organ	It was found that the intended recipient required another organ transplant in addition to the originally needed organ. The change in recipient's organ need did not allow this potential living donor to donate.
Intended recipient no longer a candidate for other reasons	The intended recipient did not proceed with the transplant using the potential living donor's organ for reasons not specified in the other categories. This could include logistical issues, changes in medical condition, or other unique factors.

Surgical Addendum

Intended Liver Surgical Information

This section displays if a liver was intended to be recovered from the donor but the procedure was aborted after anesthesia was administered.

Intended Type of transplant graft: Select the intended type of transplant graft from the drop-down list. This field is **required**.

- **Left Lateral Segment**
- **Left Lobe without MHV (Middle Hepatic Vein)**
- **Left Lobe with MHV**
- **Right Lobe without MHV**
- **Right Lobe with MHV**

Intended procedure type: Select the intended procedure type from the drop-down list. This field is **required**.

- **Open**
- **Pure Laparoscopic**
- **Hand-assisted Laparoscopic**
- **Laparoscopic-assisted Open**
- **Pure Robotic**
- **Robotic-assisted Open**

Conversion from Laparoscopic to Open: If **Laparoscopic** was selected for **Intended procedure type**, and there was a conversion from laparoscopic to open procedure, select **Yes**. If there wasn't a conversion, select **No**.

Intended Kidney Surgical Information

This section displays if a kidney was intended to be recovered from the donor but the procedure was aborted after anesthesia was administered.

Intended Type of transplant graft: Select the intended type of transplant graft from the drop-down list. This field is **required**

- **Left Kidney**
- **Right Kidney**

Intended procedure type: Select the intended procedure type from the drop-down list. This field is **required**.

- **Transabdominal**
- **Flank (retroperitoneal)**
- **Laparoscopic Not Hand-assisted**
- **Laparoscopic Hand-assisted**
- **Natural Orifice**
- **Robotic**

Conversion from Laparoscopic to Open: If **Laparoscopic** was selected for **Intended procedure type**, and there was a conversion from laparoscopic to open procedure, select **Yes**. If there wasn't a conversion, select **No**.

Intended Lung Surgical Information

This section displays if a lung was intended to be recovered from the donor but the procedure was aborted after anesthesia was administered.

Intended Type of transplant graft: Select the intended type of transplant graft from the drop-down list. This field is **required**.

- **Lobe**, **Right**
- **Lobe, Left**

Intended Procedure type: Indicate whether the procedure type was **Open** or **Video Assisted Thoracoscopic**. This field is **required**. (List of Procedure Type codes)

Conversion from Thoracoscopic to Open: If **Open** was selected for **Procedure Type**, and there was a conversion from thoracoscopic to an open procedure, select **Yes**. If there was no conversion, select **No**.

Intra-operative complications: If there were any intra-operative complications, select **Yes**. If not, select **No**. This field is **required**.

If Yes, specify: Select the complication(s) by clicking on the checkbox next to the complication. If **Other Specify** is selected, enter the name of the other complication in the **Other, specify** field.

- **Sacrifice of second lobe, specify**
- **Anesthetic complication, specify**
- **Arrhythmia requiring therapy**
- **Cerebrovasular accident**
- **Phrenic nerve injury**
- **Brachial plexus injury**
- **Breast implant rupture**
- **Other, specify**

Sacrifice of second lobe, specify: If a second lobe was sacrificed, select the type from the drop-down list.

- **RML**
- **RUL**
- **LUL**

- **Lingular**

Anesthetic complication, specify: If anesthetic complication occurred, enter the complication.
Arrhythmia requiring therapy: If there was arrhythmia requiring therapy, select the therapy from the drop-down list.

- **Medical therapy**
- **Cardioversion**
- **Other, specify**

Uterus Surgical Information
This section displays if a uterus was intended to be recovered from the donor but the procedure was aborted after anesthesia was administered.
Intended procedure type: Select the intended procedure type.

- **Robotic**
- **Hybrid**
- **Open**

Was there a conversion from Robotic to Open?: If **Robotic** was selected for intended procedure type, and there was a conversion from robotic to open procedure, select **Yes**. If there wasn't a conversion, select **No**.
Operative time (surgical time from skin to skin): Operative time is the time taken from skin incision to completion of skin closure. Enter the start and end date and time.
Ovaries removed: If ovaries were removed during uterus donation, select **Yes**. If the donor's ovaries were not removed, select **No**. If the donor's ovaries were absent at the time of uterus donation, select **N/A**.
Intra-operative complications: Intra-operative complications refer to complications occurring during operative time. If the donor experienced intra-operative complications, select **Yes**. If not, select **No**. If **Yes**, indicate the complication(s) experienced by the donor.
Ureter injury: Ureter injury refers to damage to the ureter. If a ureter injury occurred, select the type of ureter injury:

- **Unilateral**
- **Bilateral**
- **Other**

Was injury corrected?: Select **Yes** or **No**.
Anesthetic complications: If an anesthetic complication occurred, specify the complication.
Other: If other complications occurred during surgery, specify the complications.
Other VCA Surgical Information
This section displays if a vascularized composite allograft was intended to be recovered from the donor but the procedure was aborted after anesthesia was administered.
Intra-operative complications: Intra-operative complications refer to complications occurring during operative time. If the donor experienced intra-operative complications, select **Yes**. If not, select **No**. If **Yes**, indicate the complication(s) experienced by the donor.
Anesthetic complications: If an anesthetic complication occurred, specify the complication.
Other: If other complications occurred during surgery, specify the complications.