OPTN

Concept Paper

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

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Concepts for a Collaborative Approach to Living Donor Data Collection

Sponsoring Committee: *Living Donor*
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Executive Summary

Due to limited data, long-term outcomes and barriers to living donation are not well understood. To that end, the OPTN Living Donor Committee (the Committee) has sought to identify solutions to fill these current gaps in knowledge. Establishing a comprehensive understanding of long-term risks and benefits attributable to living donation as well as analysis of access and barriers to living donation could have a substantial impact to the field of transplant. With this objective in mind, the Committee presents a conceptualized future state of data collection by detailing the shared responsibility of the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry for Transplant Recipients (SRTR) Living Donor Collective in collecting data on living donor candidates and living donors. In doing so, both the OPTN and SRTR are carrying out contract tasks established by the Health Resources and Services Administration (HRSA) and recognizing their shared commitment to the transplant and living donor communities.

The conceptualized future state of living donor data collection includes the OPTN requiring collection and reporting of living donor candidate and donation decision data, which would be shared with the Living Donor Collective to establish a foundation that enables the Living Donor Collective to directly follow-up with living donor candidates and living donors long-term on a national level. The Committee's intention with this conceptualized collaborative approach is to increase efficiency, reduce redundancy, and acquire key data that the transplant and living donor communities deem important. The Committee requests feedback on the potential future state of living donor data collection described in this paper and the role that the OPTN could assume if this collaborative approach was adopted and implemented.

Need for Long-Term Living Donor Data Collection

While the benefit of living organ donation 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 understood or fully studied. Given the sacrifice of living donors and the benefit they provide to others, there must be improved understanding, monitoring, and analysis of living donor long-term outcomes beyond organ failure and death. Living donation is an entirely elective surgery that offers no physiological benefit to the living organ donor. Living donors are providing gifts of life to transplant candidates. In addition to the gift of life, living donors contribute to the transplant system by donating to one waitlisted transplant candidate, and in doing so, enable transplantation of another waitlisted transplant candidate when a deceased organ next becomes available.

Longitudinal data are necessary for improving informed consent of living donors. Living donors and potential living donors may need additional data on the lifetime implications of living organ donation. Additionally, living donors have noted that data-based disclosures not only help with their own understanding of the risk of living organ donation, but also when communicating with their families. Living donors want their families and support network to affirm their decision to donate, and to have data-based information regarding the lifetime risk and benefit of living organ donation. This will help potential living donors communicate with their families about their decision.

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.[1,2,3]

It may also safeguard living donors' long-term wellness and safety by having data to identify risk factors and long-term outcomes, which may 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. However, the Living Donor Committee (the Committee) recognizes that long-term outcomes could reveal unanticipated results that may negatively affect living donation, such as insurance companies utilizing the data to determine coverage.[4]

There have been longitudinal research studies on living donors; however, the existing research is not sufficient to extrapolate outcomes to a national cohort.[5] There is consensus in the transplant

[1] 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.
[2] 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
[3] Clemens, K., Thiessen-Philbrook, H., Parikh, C., et al.; "Donor Nephrectomy Outcomes Research (DONOR)
[4] OPTN Living Donor Committee, *Meeting Summary*, September 14, 2022. Available at https://optn.transplant.hrsa.gov/.
[5] Ibrahim, H., Foley, R., Reule, S., et al. "Renal Function Profile in White Kidney Donors: The First 4 Decades," Journal of the American Society of Nephrology. (2016):27(9), 2885–2893. doi: 10.1681/ASN.2015091018.

community that long-term data collection on living donors is necessary.[6,7,8,9,10,11] Notably, a recent multi-stakeholder consensus conference, which included 30 percent patients, was held to identify information and metrics that are relevant to the transplant community.[12] One of the recommendations from this consensus conference that arose was the need for data on long-term living donor experiences including quality of life and patient-centered outcomes. These recommendations cited that collecting long-term data on living donor outcomes is a moral and ethical obligation.[13]

In the past twenty years, members of the community have identified that the current follow-up of living donors does not provide sufficient data to understand long-term outcomes.[14,15,16,17,18,19,20,21,22] Current data available on long-term living donor outcomes are inadequate in accurately quantifying the risks and benefits that a living donor assumes when they consent to donate an organ. The need for long-term data collection on living donors has been well documented, and the Committee

[6] Takagi, K., Umeda, Y., Yoshida, R., et al. "Short-term and long-term outcomes in living donors for liver transplantation: Cohort study," *International Journal of Surgery*. 2020 Dec;84:147-153. doi: 10.1016/j.ijsu.2020.11.013.
[7] Hanson, C., Sautenet, B., Craig, J., et al. "Informative for Decision Making? The Spectrum and Consistency of Outcomes After Living Kidney Donation Reported in Trials and Observational Studies," *Transplantation*. (2019);103(2), 284–290. doi: 10.1097/TP.0000000000002489
[8] Samaniego-Picota, M., Patel, A., Davis, C. "Live Kidney Donation: Gaps Remain," *Advances in Chronic Kidney Disease* 2012 Jul;19(4)205-206. doi: 10.1053/j.ackd.2012.05.005
[9]Dew, M., Butt, Z., Humar, A., DiMartini, A. "Long-Term Medical and Psychosocial Outcomes in Living Liver Donors," *American Journal of Transplant.* 2017 Apr;17(4):880-892. doi: 10.1111/ajt.14111.
[10] Lentine, K., Schnitzler, M., Xiao, H., et al. "Racial variation in medical outcomes among living kidney donors," *The New England Journal of Medicine.* (2010);363(8), 724–732. Doi" 10.1056/NEJMoa1000950
[11] Lentine, K., Lam, N., Segev, D. "Risks of Living Kidney Donation: Current State of Knowledge on Outcomes Important to Donors." *Clinical Journal of the American Society of Nephrology*. (2019);14(4), 597–608. doi: 10.2215/CJN.11220918
[12] Snyder, J., Schaffhausen, C., Hart, A., et al. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." *Am J Transplant.* 2023.
[13] Ibid.
[14] Excerpt of Region 2's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Finally, there was general agreement that two year follow-up does not provide information that is valuable for determining donor survival rate or long-term status." (Public Comment period September 16, 2011 to December 23, 2011).
[15] Excerpt of Region 9's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "A comment was made that the laboratory tests required in this proposal are useless at the two year mark as living donors develop renal disease over a longer period of time." (Public Comment period September 16, 2011 to December 23, 2011).
[16] Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up,* "The time frame for this proposal, along with the plan to monitor compliance by peers and colleagues assigned to UNOS/OPTN Committees, will mean that in another 12 years, in 2023, another Living Donor Data Task Force (LDDTF) will likely conclude that OPTN data is 'woefully inadequate'." (Public Comment period September 16, 2011 to December 23, 2011).
[17] Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Because living donors choose to voluntarily assume a great deal of potential risk, including possible death, the medical profession should be doing everything that it can in order to help prospective donors to be accurately informed of any potential risks, including the impact on long-term health." (Public Comment period September 16, 2011 to December 23, 2011).
[18] Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "A two year study is not adequate enough to discover information that is important for the donation process and for the donor to understand." (Public Comment period September 16, 2011 to December 23, 2011).
[19] Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Hopefully in the future the period of time required for follow-up can be extended." (Public Comment period September 16, 2011 to December 23, 2011).
[20] Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "While current evidence shows that living donation does not change life expectancy and does not appear to increase the risk of kidney failure, additional data collection on the long-term outcomes for living donors is needed." (Public Comment period September 16, 2011 to December 23, 2011).
[21] Excerpt of National Kidney Foundation's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "Lifetime follow-up and data collection on the health status of donors, including blood pressure, is helpful information that may be used in the future to inform potential living donors." (Public Comment period September 6, 2013 to December 6, 2013).
[22] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "I strongly support this proposal, and hope that this minimal first step, which is merely parity with the already approved minimum followup for living kidney donors, leads to mandatory lifetime followup of all living donors and living donor candidates, past, present, and future as a condition of remaining a transplant center." (Public Comment period September 6, 2013 to December 6, 2013).

emphasizes that these data are the best way to ensure living donor safety and inform evidence-based policies.

In exploring feasible ways to enable long-term data collection, the Committee developed six findings and recommendations that have guided their subsequent discussions. These findings and recommendations were presented to the OPTN Board of Directors in December 2022[23]:

1) Living donors should be followed for their lifetimes.
2) There are barriers and burdens associated with transplant programs performing living donor follow-up.
3) A registry may be better situated to perform long-term living donor follow-up.
4) Resource constraints remain a logistical concern for long-term living donor follow-up.
5) There are opportunities for increased efficiencies and integration across organizations that support the transplant community.
6) Broader living donor engagement is necessary.

The OPTN Board of Directors was supportive of the Committee's findings and recommendations, and encouraged the Committee to continue to identify projects that may support long-term living donor follow-up.[24] Since that time, the Committee identified a project that would realign living donor data collection in an effort to establish a collaborative approach to long-term data collection on living donors.

Collaborating with and supporting living donor data collection through a national registry is not a new idea to the public. Suggestions that a national registry may be a better entity for long-term collection of living donor data have been well documented. In 2000, the Living Donor Consensus Conference endorsed a Live Organ Donor Registry to collect demographic, clinical, and outcome information on all living donors.[25] The limitations of current knowledge regarding long-term consequences of donation were part of the rationale for endorsing a national registry. This theme remains apparent over twenty years later.

In 2003, the OPTN Board of Directors adopted the following positions regarding the long-term follow-up of living donors:

- "Long-term follow-up of living donors is essential to define the risks and benefits of living donation in order to protect donors and facilitate accurate informed consent.
- Research projects using sampled data may provide important information regarding center-specific practices, but they will not ensure that quality and compliance data for all centers are captured and addressed. Only a registry collection mechanism can achieve these goals."[26]

[23] OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.
[24] OPTN Board of Directors, *Meeting Summary,* December 5, 2022. Available at https://optn.transplant.hrsa.gov/.
[25] 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
[26] OPTN Board of Directors, *Ad Hoc Living Donor Committee Report to the Board of Directors, June 26-27, 2*003.

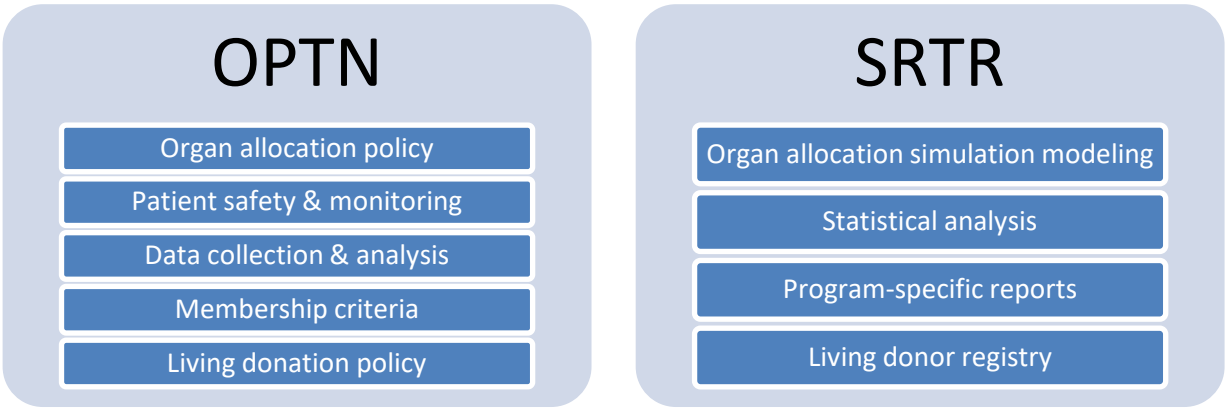
Additionally, in 2012, public comments advocated for longer-term follow-up, with suggestions of utilizing a national living donor registry.[27,28,29,30,31] While a registry is a useful mechanism to capture needed data, resources and governance to manage the registry will need to be put into place to achieve the intended results.

The following sections detail the current state of living donor data collection and the Committee's conceptualized future state. Afterwards, more specific information on the potential role of the OPTN in the conceptualized future state is outlined.

Current State

For the purposes of contextualizing different roles in living donor data collection, the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry for Transplant Recipients (SRTR) are defined here. **Figure 1** provides a summary of the roles of the OPTN and SRTR, while **Table 1** provides an overview of living donor data collection efforts by the OPTN and SRTR. 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).

Figure 1: The Roles of OPTN & SRTR



Established via 42 U.S.C. §274, the OPTN maintains the national waiting list and matches deceased donor organs with transplant candidates; collects, analyzes, and publishes data; and establishes

[27] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "We need a prospective registry of living donors now, conceptualized and managed independently from those with professional and commercial interest in transplantation." (Public Comment period September 16, 2011 to December 23, 2011).
[28] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Transplants recipients have a comprehensive and long-term registry. So do bone marrow donors. Meanwhile, despite international, medical and ethical calls for a living donor registry, living donors have been given the equivalent of a box of band-aids." (Public Comment period September 16, 2011 to December 23, 2011).
[29] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Also this conversation will stimulate early data on problems that may help to show the definite need for other means of longer term follow up, such as an OPTN national registry with more vigorous funding and data collection." (Public Comment period September 16, 2011 to December 23, 2011).
[30] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "this should be changed to form a living kidney donor registry, set up and run by a group independent of doctors, hospitals and health companies that benefit from this operation." (Public Comment period September 16, 2011 to December 23, 2011).
[31] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "I agree and we should collectively work towards a nationally funded program that would provide the resources for life-long followup of the donor after the first few years." (Public Comment period September 16, 2011 to December 23, 2011).

membership criteria and medical criteria for organ allocation.[32] In 2006, the Department of Health and Human Services (HHS) determined in a Federal Register notice that OPTN living donor guidelines should be given the same status of other OPTN policies.[33] In terms of data collection, the OPTN has the ability to require transplant programs to report specific data[34]. 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.[35] 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.[36] Additionally, SRTR piloted a living donor registry per contract requirement with HRSA. SRTR aims to study the long-term outcomes of living organ donation via this living donor registry.[37] 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.

Table 1: A comparison of current living donor data collection efforts by the OPTN and the Living Donor Collective

OPTN	Living Donor Collective
Registers living donors	Registers living donor candidates [a]
Registration is mandatory for programs	Registration is voluntary for programs
Required follow-up for living donors at 6-, 12-, and 24-months	Planned lifetime follow-up for living donor candidates and living donors

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

OPTN Living Donor Data Collection

The OPTN requires transplant programs to collect and report data on living donors (**Figure 2**).[38] The first required data reporting on 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 eleven data elements, including baseline data such as blood type, sex, date of birth, and organ type and must be submitted prior to the donation surgery.[39] Generally, the *Living Donor Feedback (Add Donor)* data is submitted once a living

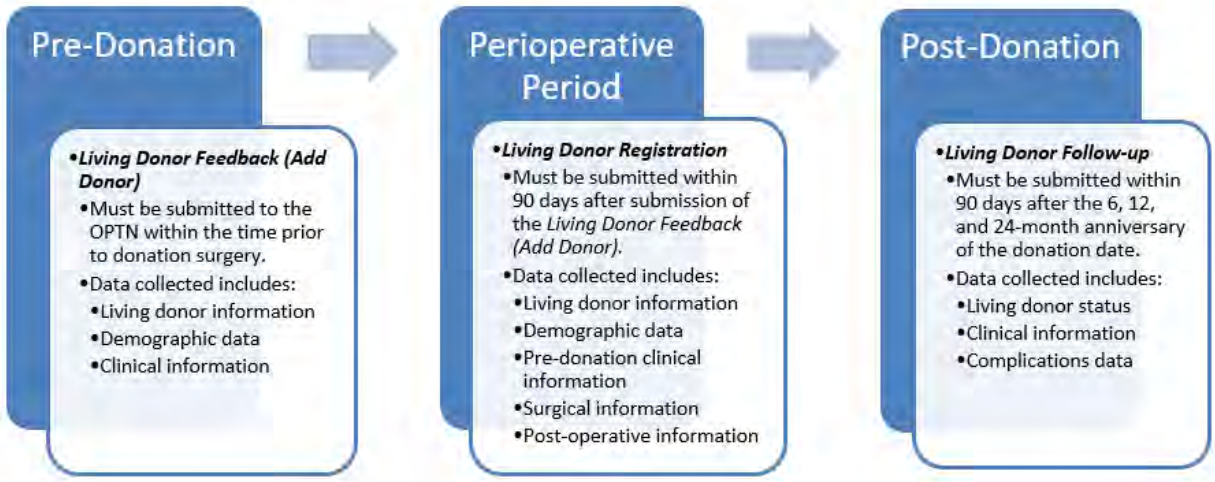
[32] 42 U.S.C. §274 – Organ Procurement and Transplant Network
[33] Department of Health and Human Services, Health Resources and Services Administration, "Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines," 71 Fed. Reg. 34946 No. 116 (June 16, 2006). https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-andtransplantationnetwork-optn-living-donor.
[34] OPTN Policy 18.4: Living Donor Data Submission Requirements; OPTN Policy 18.5: Reporting of Living Donor Events
[35] "Driven to Make a Difference: Mission, Vision, and Values", Scientific Registry of Transplant Recipients. Available at https://www.srtr.org/about-srtr/mission-vision-and-values/.
[36] Ibid.
[37] "Who We Are", Living Donor Collective: An SRTR Initiative. Available at https://livingdonorcollective.org/about-ldc/who-we-are/
[38] OPTN Policy 18.1: Data Submission Requirements
[39] OPTN Policy 18.1: Data Submission Requirements, Table 18-1: Data Submission Requirements

donation is scheduled. 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 perioperative period of the donation event, as well as demographic data. This form collects the most extensive data on living donors for the purpose of patient safety monitoring. 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, and lung donors. The *LDR* must be submitted 90 days after the *Living Donor Feedback (Add Donor)* form is submitted.[40]

Following the immediate post-operative period 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 the *LDF* is to collect data to inform the experience, safety, and health implications for living donors by comparing pre-donation data to post-donation data since no alternative source of data exists.[41] OPTN policy requires the *LDF* form to be submitted for each living donor within 90-days of the 6-, 12-, and 24-month anniversaries of the donation date.[42] The data collected in the *LDF* form include living donor status, organ-specific clinical information, and complications.

Figure 2: OPTN Living Donor Data Collection[42]



For long-term outcomes, the OPTN links data submitted through the OPTN living donor data collection forms with external data sources for outcomes such as end-stage renal disease (ESRD) and death.[43]

[40] OPTN Policy 18.1: Data Submission Requirements, Table 18-1: Data Submission Requirements
[41] OPTN Living Donor Committee, *Proposal,* Proposed Modifications to OPTN Policy 7.1.5 "Reporting Definitions" and OPTN Policy 7.3.2 "Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms".
[42] OPTN Policy 18.1: Data Submission Requirements, Table 18-1: Data Submission Requirements
[43] Under the authority granted by the Social Security Act, Section 205(r) (42 U.S.C. §405(r)(10)), the OPTN receives the full DMF file from CMS27-28. For a death record from this file to be included in the OPTN database, the OPTN is required to independently verify the death by finding an alternate/confirmatory source of this information; this process is done monthly.

SRTR Living Donor Data Collection

In 2016, HRSA charged the SRTR with establishing a national living donor candidate registry, now known as the Living Donor Collective. The project began as a pilot including ten transplant programs to develop the necessary infrastructure and processes, to assess feasibility of living donor candidate[44] registration by transplant programs, with an ultimate plan to include all living donor transplant programs in the United States.[45] Eligibility definitions and data elements for registration were determined by a steering committee that includes representatives from all transplant programs participating in the pilot project.

In addition, if donation does not occur, the Living Donor Collective obtains data on reasons a living donor candidate did not donate. Through registering living donor candidates, the Living Donor Collective is designed to not only include living donors, but also capture a control population of individuals who underwent living donor evaluation but did not donate, which may then serve as a comparator group to identify barriers to living donation as well as long term outcomes. The Living Donor Collective's data collection differs from that of the OPTN by registering living donor candidates at the time of initial evaluations and does not duplicate the short-term follow-up of the OPTN (**Table 1**). The Living Donor Collective is relatively new and data are still accumulating.

Candidate Registration

The Living Donor Collective's steering committee defined eligible living donor candidates as individuals who come to a transplant program for evaluation. Many potential living donors are screened before they come to the transplant center, but the steering committee deemed it would be challenging and less meaningful to define a living donor candidate based on information that varies and is often incompletely collected at the time of initial contact. Therefore, the Living Donor Collective adopted the above definition to enable data collection on a manageable number of living donor candidates who have undergone at least some prior screening and have a corresponding record created in an electronic health record.

In the Living Donor Collective, transplant programs are asked to collect demographic and clinical data. These data are similar to what is currently collected as part of the OPTN *LDR* form but incorporates updates in clinical practice that followed creation of the existing *LDR* form. During the pilot phase of the Living Donor Collective, the SRTR developed an independent, web-based data entry portal used by transplant programs to submit data on living donor candidates. Due to the similarities of what is collected on the Living Donor Collective's initial registration form and the *LDR* form, this highlights the duplicative data entry for those transplant programs participating in the Living Donor Collective.

Donation Decision

Transplant programs are also asked to report the reason for why a living donor candidate did not donate, with options determined by the pilot phase steering committee. This data is asked of transplant

[44] 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.

[45] 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 p. The Living Donor Collective: A Scientific Registry for Living Donors. *Am J Transplant.* 2017;17(12):3040-3048.

programs to provide when it becomes clear that a living donor candidate will not donate, or no more than two years after registration if the living donor candidate has not donated.

Follow-up Information from Surveys & Data Linkages

Under the Living Donor Collective model, follow-up information is collected by the SRTR contractor, not by transplant programs. The Living Donor Collective will establish procedures for maintaining contact with participants using a brief survey form. Contact is anticipated by email, telephone, or mail 1 year after donation or 1 year after determination of non-donation, and every 1-2 years, thereafter. Additional methods of contact such as text messaging may be developed based on stakeholder feedback. The pilot phase of the Living Donor Collective focused on living donor candidate registration. In the next phase, the plan is to collaborate with stakeholders including the OPTN Living Donor Committee and the Living Donor Collective's Donor and Transplant Program Advisory Committees, to develop a comprehensive follow-up survey form. The comprehensive survey will be administered to all participants at intervals yet to be determined to maximize the amount of accrued follow-up information on potential long-term complications of donation.

The Living Donor Collective will also develop and administer surveys addressing specific complications of interest and importance to living donors. For example, a recent meta-analysis found preeclampsia is more common in living kidney donors than in the general population, including women selected as controls by baseline good health similar to living donors[46], and a development of a pregnancy registry has been proposed in a recent American Society of Transplantation (AST) controversies conference.[47] Therefore, the Living Donor Collective will place a high priority on establishing the risk of living kidney donation with regard to pregnancy, working with stakeholders to develop a survey form for pregnancy complications for all female living donors of reproductive age.

To determine which living donor candidates develop end-stage organ failure, the Living Donor Collective will link living donor candidate registration data to Centers for Medicare and Medicaid Services (CMS) End-stage Renal Disease reporting forms (Form 2728), along with OPTN data for transplant candidate listing and transplantation events (all solid organs). In addition, the Living Donor Collective will link living donor candidate registry data to national death records to obtain data on deaths and causes of death among living donors. For other complications, the SRTR contractor will link registry data to a Pharmaceutical Claims Data (PCD) clearinghouse. The PCD collects prescription drug fill records reimbursed by private payers, public payers, and self-paid fills, and has been explored in pilot form to describe several exposures and outcomes of interest in living donors, such as pharmaceutical treatments for depression,[48] hypertension,[49] diabetes,[50] gout,[51] and pain.[52,53] Other public and private data sources

[46] Snyder, J., Schaffhausen, C., Hart, A., et al. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." *Am J Transplant.* 2023.
[47] A pregnancy registry for transplant recipients does exist; However, there is not a comparable pregnancy registry for living donors. More information on the pregnancy registry for transplant recipients is available here: https://www.transplantpregnancyregistry.org/.
[48] Lentine, K., Schnitzler, M., Xiao, H., et al. "Depression diagnoses after living kidney donation: linking U.S. Registry data and administrative claims." *Transplantation.* 2012;94(1):77-83.
[49] Lentine, K., Schnitzler, M., Garg, A., et al. "Understanding antihypertensive medication use after living kidney donation through linked national registry and pharmacy claims data." *American journal of nephrology.* 2014;40(2):174-183.
[50] Ibid.
[51] Lam, N., Garg, A., Segev, D., et al. "Gout after living kidney donation: correlations with demographic traits and renal complications." *American journal of nephrology.* 2015;41(3):231-240.
[52] Lentine, K., Lam, N., Schnitzler, M., et al. "Gender differences in use of prescription narcotic medications among living kidney donors." *Clinical transplantation.* 2015;29(10):927-937.
[53] Lentine, K., Lam, N., Schnitzler, M., et al. "Predonation Prescription Opioid Use: A Novel Risk Factor for Readmission After Living Kidney Donation." *Am J Transplant.* 2017;17(3):744-753.

will also be used as available to obtain long term follow-up information on registered living donor candidates and living donors.

Maintaining Relevancy for Stakeholders

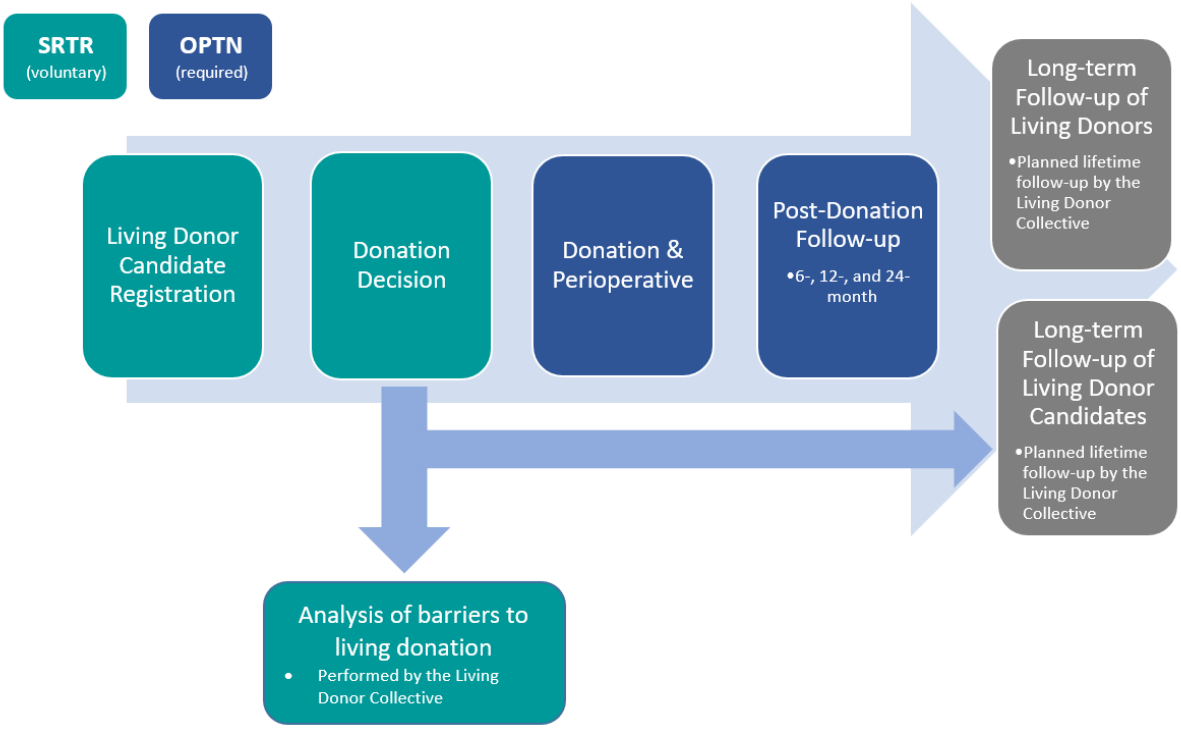
To better understand what is most important to potential living donors and living donors, the Living Donor Collective is creating advisory groups composed of prior living donors (patient advisory) and transplant program staff (program advisory), including representation from the OPTN Living Donor Committee. These advisory groups will help to determine what questionnaires and follow-up information is most important to living donors, discuss modalities for contact and maintaining engagement with living donors and living donor candidates who do not donate, and other processes (e.g., living donor candidate registration data collection by programs). In addition, the Living Donor Collective maintains a website to provide the latest information of importance to living donors, focusing not only on outcomes but also on other issues and information that may be helpful, such as information on kidney paired donation programs, the National Living Donor Assistance Center, and other information sources.[54]

Current State Overview

In summary, all living donor transplant programs report data to the OPTN as required by OPTN policy, and some transplant programs report data to the SRTR voluntarily as part of the Living Donor Collective. **Figure 3** provides a visual for the current state of living donor data collection via the OPTN and SRTR. Specifically, the Living Donor Collective collects living donor candidate and donation decision data via voluntary transplant program participation. The OPTN requires collection of perioperative donation data as well as data 6-, 12-, and 24-months after the donation event. The Living Donor Collective also collects follow-up data via an annual follow-up survey to living donor candidates and living donors. The Living Donor Collective is seeking to expand their current follow-up initiatives.

[54] Living Donor Collective: An SRTR Initiative. Available at https://www.livingdonorcollective.org/.

Figure 3: Current State of Living Donor Data Collection via the OPTN and SRTR



Additionally, both the OPTN and SRTR can perform data linkages. To create a more robust data set, OPTN and SRTR datasets can be linked with external sources of data. While there are some overlaps, the SRTR intends to establish data linkages beyond those that are currently established within the OPTN. More detailed information on the current state of data linkages can be found in the respective sections above.

Based on the current state, the Committee analyzed possible solutions to collect living donor data past the current 24-month required reporting. Further information regarding the Committee's discussions on the potential to expand required follow-up via transplant programs can be found in the section *Other Concepts Considered* on page 19. Thus, the Committee has sought how to align with other community resources to acquire key data and reduce redundancies.

Conceptualizing a Collaborative Future State

The concepts detailed in this paper align with the Committee's goals of analyzing risks and benefits attributable to living donation, as well as analyzing access and barriers to living donation. To achieve these goals, the Committee opted to pursue a project with the intention of increasing efficiency, reducing redundancy, and acquiring key data the transplant and living donor communities seek. While the concepts outlined below are a new approach to living donor data collection, it is not the Committee's intent to increase the workload of transplant programs and efforts to improve efficiency will be prioritized.

This paper details concepts and is not a final proposal. The Committee urges the community to consider these concepts and provide feedback on how best to achieve acquiring the data that have been repeatedly deemed to be necessary. It is important to understand the Committee's intent of the

proposed project concepts and how it would function with broader community collaboration to align with the goal of understanding long-term living donation outcomes.

An overview of how the Committee envisions a future state of living donor data collection is described below. After the overview section, the specifics of two separate, but related, projects are detailed.

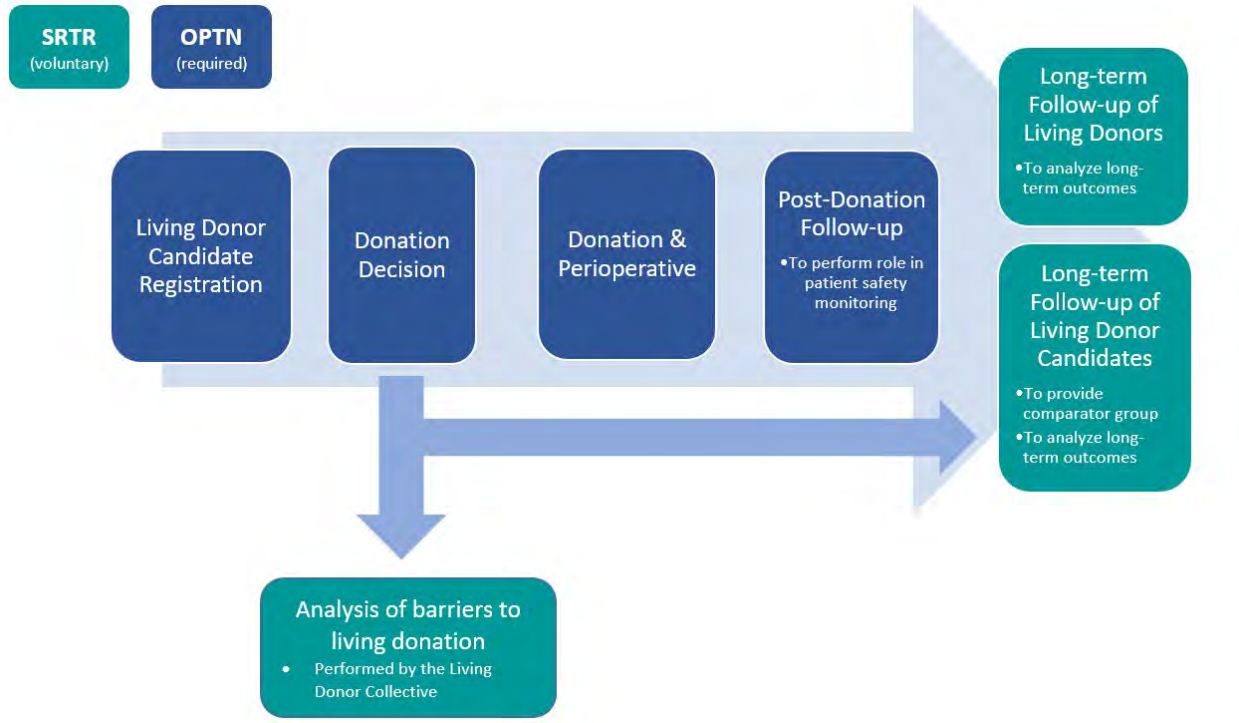
Future State Overview

Due to the significant barriers associated with collecting extended living donor follow-up by transplant programs juxtaposed with the consensus that longer-term data are needed, the Committee determined that some other entity, such as a registry, may be better situated to connect directly with living donors.[55] To that end, the Committee has been collaborating with the SRTR to conceptualize this future state of living donor data collection. Since the Living Donor Collective is a voluntary living donor registry, it has been difficult to engage transplant programs to participate while simultaneously meeting OPTN data collection requirements. Thus, the Committee proposes the concept of shifting current OPTN living donor data collection requirements to earlier in the living donor evaluation process (upstream) in an effort to support the Living Donor Collective as the national living donor registry performing long-term follow-up. With the additional goal of improving efficiency, areas of redundancy or overlap involving current OPTN and SRTR can be identified and eliminated.

Figure 4 provides a visualization of the main concept detailed in this paper. This visual shows that the OPTN would require collection and reporting of living donor candidate and donation decision data. These data would be shared with the Living Donor Collective to establish a foundation in which the Living Donor Collective could directly follow-up with living donor candidates and living donors long-term at a national level.

[55] OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.

Figure 4: Concept of future state of living donor data collection via the OPTN and SRTR



Expanding required OPTN data reporting upstream may allow for the Living Donor Collective to focus solely on the follow-up of living donor candidates and living donors. The Committee recognizes and supports the OPTN role in monitoring patient safety events in the perioperative period and is not contemplating changing data reporting for this timeframe (6-months).[56] The Committee seeks feedback on whether the current required 12- and 24-month data collection for living donor follow-up are necessary and valuable to the community. If it is determined that it may not be necessary for the OPTN to require 12- and 24-month follow-up data collection for living donors, there are many different transition periods that could be enacted to ensure the Living Donor Collective is adequately supported to take over living donor follow-up. For example, a potential transition plan could have the OPTN retain the current required follow-up until it is established that the Living Donor Collective has proven acceptable follow-up rates to ensure that there would not be a lapse in living donor follow-up.

In this conceptualized future state of living donor data collection, the Living Donor Collective would perform the long-term follow-up of living donor candidates and living donors. The Living Donor Collective would engage in a patient-centered approach with living donor candidates and living donors by way of surveys administered through email, telephone, or mail.

The follow-up experience in the Living Donor Collective is preliminary, as the pilot phase has focused on living donor candidate registration and composition. The Living Donor Collective seeks to collaborate with stakeholder OPTN committees and the transplant community to enhance the necessary follow-up data forms. This conceptualized future state supports the Living Donor Collective to become a national

[56] OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.

living donor registry and would allow the Living Donor Collective to allocate additional resources for follow-up activities.

Additionally, in terms of previously described data linkages, the SRTR and OPTN will coordinate data linkages related to long-term living donor candidate and living donor outcomes to enhance data analyses and reduce any redundancy of both contractors potentially performing the same data linkages.

The Committee notes that logistical and transparency issues, such as the process of modifying data collection captured within the Living Donor Collective, will need to be addressed. For example, the OPTN is required to submit any changes to data collection for public comment to solicit community feedback; the SRTR is not beholden to the same processes. However, the Committee noted that addressing these issues is feasible and the need for long-term data surmounts any accompanying issues.

Collect Living Donor Candidate & Donation Decision Data

The Committee is requesting feedback on the concept of the OPTN collecting upstream data on living donor candidates, as well as their donation decision.

A main reason to begin collecting data on living donor candidates rather than limiting only to living donors is that it is important to assess whether the reasons some living donor candidates do not donate are potentially modifiable, and to track these patterns over time. Only by following living donor candidates who were turned down or decided not to donate due to concerns that living organ donation would adversely affect their health can it be determined whether those concerns were justified and provide the information for transplant programs to overcome modifiable barriers to living donation.

Secondly, registering living donor candidates will allow collection of follow-up information on living donor candidates who end up not donating. Fully evaluated living donor candidates who do not donate for reasons unrelated to the risk of donation (e.g., when there were other living donors for the candidate including a deceased donor, or the candidate did not undergo transplantation) can offer a suitable control group for long-term outcomes. Stakeholders in collection of these data include not only current living donors, but also future living donor candidates and living donors, patients in need of transplantation, families, healthcare providers, payers, and the general public. The previously mentioned multi-stakeholder consensus conference on metrics relevant to the transplant community that included 30 percent patients, advocated for moving living donor data collection upstream and downstream from the current mandated OPTN data collection.[57]

Living Donor Candidate Definition

The Committee proposes defining an individual who was seen at a transplant program for evaluation as a "living donor candidate".[58] The definition of a living donor candidate is important because it will indicate the point in time when required collection and reporting of data would occur. The Committee seeks to further specify this definition with the help of the transplant community. Specific feedback, also detailed at the end of this concept paper, is sought regarding the terminology, the point in time this

[57] Snyder, J., Schaffhausen, C., Hart, A., et al. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." *Am J Transplant.* 2023.
[58] OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at https://optn.transplant.hrsa.gov/.

definition indicates, as well as further defining the term *evaluation*. The Committee recognizes that living donor programs may have internally established definitions for *living donor candidate, potential living donor,* and *evaluation* and requests the community provide these definitions in order to inform accurate terminology and definition which align with the majority of the current practice.

The proposed definition also aligns with how the Living Donor Collective defines living donor candidate.[59] Capturing data at this stage in the process will allow for analysis on access and barriers to living donation as it encompasses individuals who do not proceed to living donation. While it would not encompass all information on barriers to living donation due to the specific time point indicated, the Committee agreed that collecting data on the volume of this population would be more manageable than earlier phases in the living donation process.[60] Additionally, the Committee reasoned that this definition would provide a balance between meaningful data collection and data collection burden.

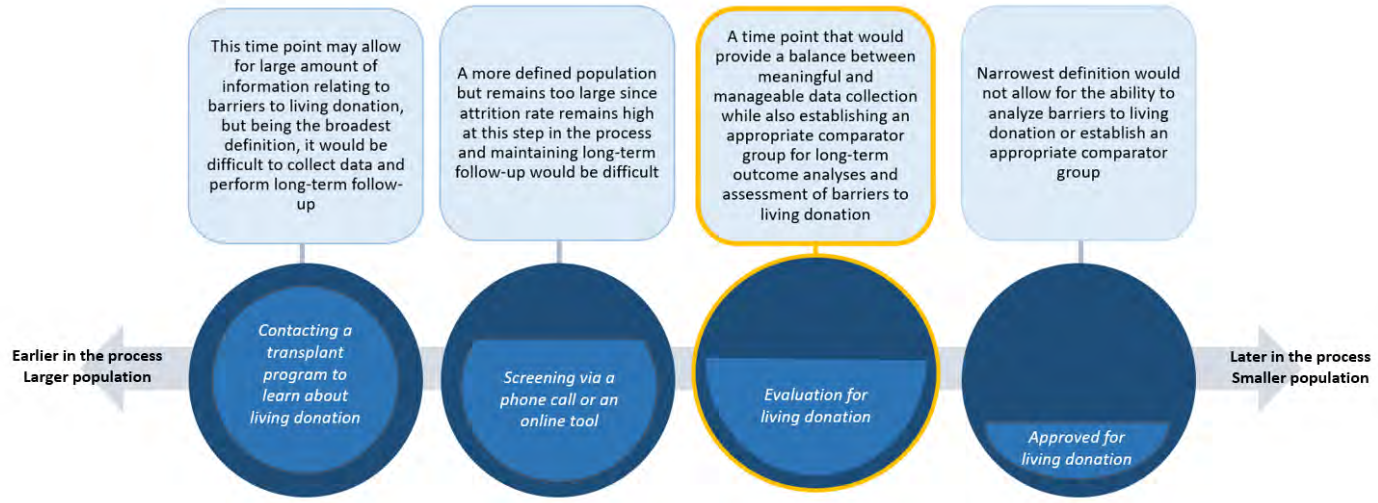
At this point in time, living donor programs are interacting with the individuals and are initiating early data collection that could be streamlined into OPTN reporting. Additionally, the Committee notes that individuals who undergo evaluation are more invested at this part of the process and may be more likely to engage in long-term follow-up regardless of whether they proceeded with donation or not.[61]

The Committee notes that collecting data on this population of individuals may allow for an appropriate comparator group.[62] Identifying an appropriate comparator group is important because comparing prior living donors to the general population presents limitations due to the prior living donor population tending to have a higher overall wellbeing. Collecting data on living donor candidates who are seen at transplant programs for evaluation creates an appropriate comparator group because these individuals undergo extensive clinical testing. Candidates for living donation who do not donate for reasons unrelated to their health are the best possible controls to compare outcomes of living donors. Additionally, this population may allow for analysis of barriers to living donation beyond medical reasons, which are often screened out earlier in the living donation process.

Initial feedback from the OPTN Transplant Coordinators Committee suggested aligning a definition of *evaluation* to the current practice of living donor programs.[63] For example, CMS conditions of participation outlines specific criteria that transplant programs must meet before evaluation can be initiated. However, CMS does not specifically define the living donor evaluation, and transplant programs use internal definitions for evaluation to align with CMS as a result. Additionally, the OPTN Transplant Coordinators Committee suggested that it may be beneficial to specify *completed evaluation* because some individuals do not finish the evaluation process due to various reasons.[64] The Committee seeks feedback on how transplant programs are defining *evaluation* in their internal processes. The Committee considered alternative definitions which are summarized in **Figure 5**.

[59] This definition was developed by a steering committee made up of transplant programs who participated in the pilot phase of the Living Donor Collective.
[60] OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at https://optn.transplant.hrsa.gov/.
[61] Ibid.
[62] Ibid.
[63] OPTN Transplant Coordinators Committee, *Meeting Summary,* May 18, 2023. Available at https://optn.transplant.hrsa.gov/.
[64] Ibid.

Figure 5: Summary of Committee Considerations for "*Living Donor Candidate*" Definition



The Committee first began considering defining a living donor candidate as an individual who contacted a living donor program to learn more about the living donation process. The Committee concluded that this definition was too broad and would encompass too large of a population.[65] When an individual contacts a living donor program to learn more about the living donation process, they have not yet made the decision to move forward with becoming a living donor. The stage of the process is largely information gathering, and thus there is a high attrition rate to moving forward to an initial screening process. Based on the number of individuals who do not move forward in the living donation process, tracking long-term outcomes would be arduous. The Committee also cited concerns that a definition starting at this point in the process could encompass the scenarios where a potential transplant recipient has hundreds of potential living donors come forward due to a social media campaign.[66] The Committee does not intend to require transplant programs to collect data on large volumes of living donor candidates. The Committee did recognize that capturing data at this stage in the process may give the most holistic view on understanding why an individual does not proceed to further screening, testing, or living donation.[67] However, due to the reasons above the Committee ultimately decided to forgo this definition.

The Committee then considered defining a living donor candidate as an individual that underwent a screening, whether that was via a phone call or an online tool. While this definition would narrow the population, the Committee decided that this definition was also over-inclusive.[68] Collecting data on individuals who underwent an initial screening may allow for a broader understanding of reasons for declines or failure to progress to living donation. However, published literature establishes a broad understanding of why individuals are screened out during this phase of the living donation process.[69] Additionally, the attrition rate at this stage remains high as most individuals may not follow through

[65] OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at https://optn.transplant.hrsa.gov/.
[66] Ibid.
[67] Ibid.
[68] Ibid.
[69] Kim, J., Kim, S., Genyk, Y. & Maw, T. (2020). The need for a living donor wellness program. *Current Opinion in Organ Transplantation, 25* (4), 311-315. doi: 10.1097/MOT.0000000000000779.

with evaluation and living donation. If an individual does not follow-up, then there is no way to understand the barrier for why they did not proceed. The Committee reasoned that if an individual is not following up at this stage in the process, it will likely be difficult to engage them in long-term follow-up.[70]

The Committee also considered a living donor candidate definition to be an individual who underwent evaluation and was approved for living donation. The Committee decided that while this definition would be an improvement from the current state of when OPTN living donor data collection begins, this definition would be too late to capture meaningful data.[71] The Committee reasoned that individuals who underwent evaluation and were approved for living donation almost all proceed to surgery.[72] Therefore, it would miss the opportunity to analyze barriers to living donation, a critical part of the Committee's goals.

Living Donor Candidate Data Collection

The Committee seeks to balance living donor candidate data collection with transplant programs' resources by determining the minimum amount of necessary data collection for living donor candidates. To help with this determination, the Committee reviewed pre-donation living donor data collection within the OPTN and SRTR systems. **Appendix A** provides a crosswalk of pre-donation living donor data elements and data forms. The Committee seeks feedback on what the community determines to be the minimum necessary amount of data to collect on living donor candidates.

The Committee wants to ensure that the added burden on transplant programs is minimized while also collecting key factors that help identify barriers to living donation and understand baseline risk factors that allow for a longitudinal comparison of living donors candidates and living donors. To that end, the Committee requests feedback on how best to approach this data collection to increase efficiency and reduce redundancy while also collecting the key data.

The following paragraphs provide an estimation on the amount and type of data that the Committee proposes to be collected and reported on living donor candidates. Much of the Committee's estimations are based on the current data collected via the *Living Donor Feedback (Add Donor)* and *LDR* forms, which also is the basis for the Living Donor Collective's initial living donor candidate registration form. The Committee's goal is to maintain a single integrated approach in which there would be no redundancy in data entry and avoidance of inputting the same data point into multiple systems (i.e., OPTN and SRTR).

The Committee proposes adding approximately 20 general data elements, with over half of these capturing basic contact information data elements in order to establish methods for future follow-up.[73] Since these data support Living Donor Collective's ability to perform long-term follow-up with living donor candidates and living donors, it is important to collect detailed contact information at the front end.[74] Collecting information on a living donor candidate's preferred method of contact as well as back-up contact information will aid in the Living Donor Collective's efforts to follow-up with living donor

[70] OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at https://optn.transplant.hrsa.gov
[71] Ibid.
[72] Ibid.
[73] OPTN Living Donor Committee, *Meeting Summary*, Month 17, 2023. Available at https://optn.transplant.hrsa.gov/.
[74] Ibid.

candidates and living donors long-term. Other data elements incorporated in this estimation include information such as name, social security number, and organ type.

For demographic data, the Committee estimates shifting approximately 5 – 10 data elements necessary to collect on living donor candidates, including information such as sex, social support, health insurance, and education level.[75] Demographic data are critical to understand barriers and access to living donation. The Committee supports collecting demographic data on living donor candidates because it may help the ability to assess change in the living donor population which could support the development of programs to increase living donation for populations that donate less frequently.[76] Demographic data would also provide more information on social determinants of health and provide context for clinical information.

In terms of clinical information, the Committee estimates collecting approximately 10 – 15 data elements necessary for all living donor candidates.[77] This would include clinical information such as blood type, history of cancer, tobacco use, diabetes, and hypertension. Clinical data are necessary because they may allow the ability to analyze potential risk factors for living donors who experience worse outcomes. Additionally, the Committee supported collecting clinical data on living donor candidates because that would allow for the opportunity to compare clinical change pre- and post-living organ donation.[78] The Committee requests community input on the most efficient and effective ways to collect clinical data. The Committee recognizes information such as hypertension is important but wants to ensure that the burden associated with collecting it remains low while the data remain meaningful.

The Committee proposes collecting some organ-specific clinical data on living donor candidates and seeks the community's feedback on what clinical data is necessary to collect on living donor candidates specific to their intended organ donation.

Additionally, the Committee discussed the potential to collect psychosocial data on living donor candidates.[79] The Committee recognizes the importance of this data but as noted several times, seeks to collect the minimum data necessary. During the evaluation phase of living donation, psychosocial information is gathered such as mental health history, substance use history, potential financial impact on donation, and social support. The Committee suggests that mental health information may be the most important to collect and seeks the community's feedback on whether to include any psychosocial data, and if so, what.

The Committee also considered that data collected on living donor candidates who do not proceed with donation could be different than the data collected on living donor candidates who go on to donate.[80] For example, a more limited data set could be acceptable for living donor candidates who do not proceed with donation. While a more detailed set of data would be necessary for the living donor candidates that continue to living organ donation. This variation in data collection could occur once the transplant program has indicated the donation decision.

[75] OPTN Living Donor Committee, *Meeting Summary*, Month 17, 2023. Available at https://optn.transplant.hrsa.gov/.
[76] OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at https://optn.transplant.hrsa.gov/.
[77] OPTN Living Donor Committee, *Meeting Summary*, May 17, 2023 Available at https://optn.transplant.hrsa.gov/.
[78] OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at https://optn.transplant.hrsa.gov/.
[79] OPTN Living Donor Committee, *Meeting Summary*, May 17, 2023 Available at https://optn.transplant.hrsa.gov/.
[80] OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at https://optn.transplant.hrsa.gov/.

Donation Decision Data

As noted earlier, one of the Committee's goals is to understand access and barriers to living donation. While some barriers to living donation are well documented in literature, there remain gaps in understanding of other barriers, such as insurance coverage.[81]

Collecting a living donor candidate's donation decision will allow for a more holistic analysis on reasons that some living donor candidates do not proceed to living donation. Having the ability to track trends in donation decisions may help inform whether there are opportunities to improve access to living donation. As shown in **Figure 3**, the Living Donor Collective is currently collecting donation decisions from participating transplant programs.[82, 83] The proposed concept (**Figure 4**) would require transplant programs to report donation decision and reason why for all living donor candidates to the OPTN in order to create a national understanding of access and barriers to living organ donation.

The Committee notes that this data may not be necessary to collect indefinitely.[84] After a certain period of time, barriers to living donation may become evident in which case donation decision may no longer need to be required data collection.

Follow-up

Fully understanding the risks of living donation supports informed consent, living donor candidate selection, shared decision making, and post-donation care. Towards that goal, the transplant community can best fulfill ethical obligations to seek the most complete information possible on the effects of donation on living donors by instituting a comprehensive national registry.

Potentially important effects of living organ donation on outcomes such as death, kidney failure, or liver failure are expected to be infrequent among living donors screened to be healthy, and therefore large numbers of living donors need to be followed for long periods of time to measure donation-attributable risks and benefits for outcomes important to living donors.

Finally, practices evolve and so will the evaluation and selection of living donor candidates in the future. Therefore, it is not sufficient to study the outcomes of potential living donors and living donors over a limited period of time. There will be an ongoing need to understand the effects of changes in the community's evaluation and selection process, and it will be important to continue to monitor outcomes of future potential living donors and living donors. As long as living donation is practiced, there will be a need for comprehensive follow-up.

While the content of project would require living donor candidate and donation decision data collection, the central part of this concept is long-term follow-up. It is worth reiterating that the rationale for OPTN requiring living donor candidate data collection is to support the Living Donor Collective to take on long-term follow-up of living donor candidates and living donors at a national level. To support this shift in

[81] Orandi, B., Reed, R., Qu, H., et al. "Donor-reported barriers to living kidney donor follow-up," *Clinical Transplantation*. 2022 May;36(5):e14621. doi: 10.1111/ctr.14621.
[82] Kasiske, B., Ahn, Y., Conboy, M., et al. (2021). "Outcomes of living liver donor candidate evaluations in the Living Donor Collective pilot registry." *Clinical transplantation*, *35*(9), e14394. https://doi.org/10.1111/ctr.14394
[83] Kasiske, B., Ahn, Y., Conboy, M., et al. (2021). "Outcomes of Living Kidney Donor Candidate Evaluations in the Living Donor Collective Pilot Registry." *Transplantation direct*, *7*(5), e689. https://doi.org/10.1097/TXD.0000000000001143
[84] OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at https://optn.transplant.hrsa.gov/.

data collection, the Committee is considering necessary trade-offs in terms of resources needed and data collected.

In terms of the resources needed to support the concepts, the Committee encourages the community to weigh in on the potential to scale back the OPTN's required follow-up to focus on patient safety monitoring (i.e., maintain only the 6-month living donor follow-up reporting requirements). This may allow transplant programs to shift resources to collecting living donor candidate and donation decision data. With the OPTN registering living donor candidates, it would allow the Living Donor Collective to pivot resources to support the shift in 12- and 24-month follow-up data collection and beyond. When considering the data collected, the Committee encourages the community to consider the type of follow-up data collected by the Living Donor Collective compared to the OPTN. For example, the *LDF* form includes clinical and laboratory data elements required for transplant programs to report, while the Living Donor Collective relies on self-reported data from living donor candidates and living donors. If the Living Donor Collective decided, in collaboration with OPTN committees and the transplant community, to collect laboratory data for long-term follow-up, then it would rely on living donor candidates and living donors to self-report this data. However, the Living Donor Collective is committed to performing long-term follow-up through patient-centered approaches, therefore, the longer-term follow-up in combination with multiple avenues of data linkages provided by the Living Donor Collective may be a worthy trade-off.

Concisely, it may be necessary to realign resources to enable upstream data collection to support the Living Donor Collective in long-term follow-up, which may result in a trade-off of current 12- and 24-month follow-up data reported to the OPTN.

Other Concepts Considered

The Committee also considered the potential of expanding living donor follow-up requirements for transplant programs. However, the Committee agreed that there are significant barriers and burdens with transplant programs collecting longer-term living donor data collection.[85] While the OPTN has been collecting living donor follow-up data since 1999, it was not until 2005 that the OPTN required living donor programs to submit follow-up data on living donors. Subsequent data from 2006 to 2009 demonstrated that many living donor programs were not reporting meaningful living donor follow-up information at the required intervals (6-, 12-, and 24-months post-donation[86]).[87] As a result, the OPTN Board of Directors approved two proposals that established minimum reporting requirements for living kidney and liver donor follow-up.[88, 89]

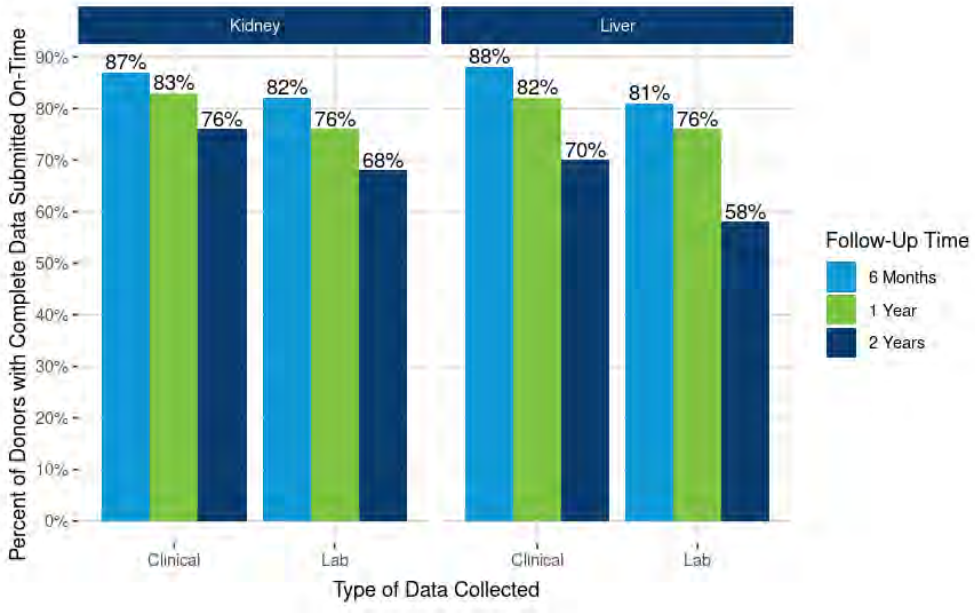
The rate of data completion submitted to the OPTN on short-term (6-, 12-, and 24-month) outcomes of living donation has increased since the implementation of Policy *18.5: Living Donor Data Submission Requirements*. After implementation of Policy 18.5 follow-up rates for living kidney donors increased from approximately 40 percent in 2006 to over 80 percent in 2019.[90] However, the data demonstrate that collecting follow-up information becomes more challenging as more time

[85] OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.
[86] OPTN Policy 18.1.B: Timely Submission of Certain Data, Table 18-1: Data Submission Requirements
[87] OPTN Living Donor Committee, *Briefing Paper,* Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up. Public Comment September 16, 2011 to December 23, 2011.
[88] Ibid.
[89] OPTN Living Donor Committee, *Briefing Paper,* Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up. Public Comment September 6, 2013 to December 6, 2013.
[90] OPTN data as of July 2022.

passes after donation.[91] Analyses of living donor characteristics also found that even shorter-term follow-up rates may vary by clinical and demographic characteristics.[92] This is necessary to note when considering the possibility of extending required living donor data collection via transplant programs past 24-months.

In 2019, the most recent full year not impacted by the COVID-19 pandemic, transplant programs submitted on time, complete OPTN living donor clinical data for 87 percent of living kidney donors at 6-months after donation, 83 percent of living kidney donors at 12-months after donation, and 76 percent of living kidney donors at 24-months after donation. These clinical data include any kidney complications or readmissions, whether the living donor has developed hypertension that requires medication, whether the living donor is working, and other information. Laboratory data submission patterns for living kidney donors are similar, but with slightly lower rates (82 percent, 76 percent, and 68 percent at 6-, 12-, and 24-months after donation, respectively). Laboratory data include serum creatinine and urine protein. OPTN follow-up rates for living liver donors are also similar, but with lower 24-month laboratory data submission rates. This may be due to differences in the timeframes established in policy for reporting thresholds; mandatory reporting thresholds for living liver donor data collection apply to 6 and 12-months[93], while mandatory reporting thresholds for living kidney donors apply to 6-, 12-, and 24-months.[94]

Figure 6: 2019 OPTN On-Time and Complete LDF Submission Rates by Organ, Follow-Up Time, and Data Type[95]



[91] Henderson, M., Thomas, A., Shaffer, A., et al. "The National Landscape of Living Kidney Donor Follow-Up in the United States," *American Journal of Transplant*. 2017 Dec;17(12):3131-3140. doi: 10.1111/ajt.14356.
[92] Reed, R., Shelton, B., MacLennan, P., et al. "Living Kidney Donor Phenotype and Likelihood of Postdonation Follow-up," *Transplantation*. 2018 Jan;102(1):135-139. doi: 10.1097/TP.0000000000001881.
[93] OPTN Policy 18.4.B: Reporting Requirements after Living Liver Donation
[94] OPTN Policy 18.4.A: Reporting Requirements after Living Kidney Donation
[95] OPTN data as of July 2022.

While transplant programs are mandated to meet specific thresholds for *LDF* data submission, current compliance declines with each required follow-up reporting period.[96] These challenges and costs become more significant as required living donor follow-up periods increase. The Committee noted that while transplant programs are mandated to report living donor follow-up, transplant programs cannot require living donors to visit for follow-up. Living donors may not be local to the transplant program because they either traveled for donation or moved post-donation. Living donors may also seek healthcare via their established primary care provider. Financial coverage of the follow-up appointments may be an additional barrier. These challenges reflect the reasons transplant programs may not be the best vehicles for collecting these data long-term.

Previous efforts to address living donor follow-up via transplant programs have been contentious given the compulsory responsibility that would be placed on transplant programs.[97,98] A similar sentiment arose during a 2010 consensus conference which noted that transplant programs would not be effective in maintaining an unfunded mandate for long-term living donor follow-up.[99] The Committee determined that another mechanism for long-term data collection of living donors needed to be identified and supported as transplant programs may not be the effective vehicle for maintaining long-term follow-up of living donors.

Granular Review of OPTN Living Donor Data Collection

The Committee's second effort is a granular review of OPTN living donor data collection forms. The Committee, in conjunction with the Living Donor Data Collection Workgroup (the Workgroup) is reviewing data elements on the *Living Donor Feedback (Add Donor)*, *LDR*, and *LDF* forms. These data collection forms have been irregularly updated since initial development, and a comprehensive review of all OPTN living donor data collection forms has never been performed. In order to ensure that the data elements on these forms are accurate, reliable, approachable, and relevant, a systematic granular review of the data is necessary.

In a future proposal, the Committee will provide recommendations to modify, add, or remove data elements from these three data forms. Additional recommendations include updates to data definitions and the structure of the forms for ease of data entry. The Committee has not yet concluded their review, and is seeking public comment feedback, specifically from living donor program staff who interact with these forms, on modifications, additions, or removals of data elements and data definitions currently in the system.

The Committee reviewed the OPTN Data Collection Principles[100] and identified the following principles which justify the OPTN collecting living donor data:

1) Determine member-specific performance;

[96] Refer to **Figure 6:** 2019 OPTN On-Time and Complete LDF Submission Rates by Organ, Follow-Up Time, and Data Type.
[97] Excerpt of OPTN Transplant Administrators Committee's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "The Committee did not support this proposal as written and has the following comments for the LDC to consider, Unfunded mandate." (Public Comment period September 16, 2011 to December 23, 2011).
[98] Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "So, it seems rather punitive to me to ask the transplant programs to cover this financially and then be "blamed" if they cannot get the donors to respond." (Public Comment period September 6, 2013 to December 6, 2013).
[99] Living Kidney Donor Follow-Up Conference Writing Group, Leichtman, A., Abecassis, M., Barr, M., et al. "Living kidney donor follow-up: state-of-the-art and future directions, conference summary and recommendations," *American Journal of Transplant.* 2011 Dec;11(12):2561-8. doi: 10.1111/j.1600-6143.2011.03816.x.
[100] OPTN Board of Directors, *Meeting Summary,* June 2006.

2) Ensure patient safety when no alternative sources of data exist;
3) Develop transplant, donation, and allocation policies.[101]

To date, the data elements reviewed by the Committee and the Workgroup are outlined in **Appendix B**. The Workgroup includes representation from the OPTN Data Advisory and Transplant Coordinators Committees as well as Living Donor Collective representatives. The Committee will continue the collaborative review and engage additional feedback from organ-specific stakeholders on relevant clinical data elements. Review of these elements will inform a public comment proposal to ensure accurate and effective OPTN data collection for living donors.

Next Steps

The Committee urges the community to consider these concepts and provide feedback on the opportunities to operationalize a living donor data collection system that will increase efficiency, reduce redundancy, and acquire key data. The Committee is interested in engaging the community and collaborating with the Living Donor Collective in order to move towards a future state of long-term living donor data collection.

Additionally, the Committee urges the living donor population to provide their feedback on how they seek to engage in long-term follow-up. Central to the Committee's discussions is the need to engage the broader living donor population. The Committee recognizes that what transplant professionals seek in long-term data collection may be different than what living donors find to be important. Engagement and input directly from living donors is imperative in creating a holistic long-term data collection effort. With living donor input, future data collection may help with living donation decision-making, as well as post-donation health care. The Committee seeks feedback from living donors in order to create a collaborative and meaningful solution to long-term data collection.

Collecting data on living donor candidates and donation decision is a significant and substantive change compared to the current data collection structure. Updating OPTN living donor data collection forms would require updates to data elements in the currently existing OPTN data collection structure. However, if the community is supportive of the former, there is opportunity to combine these projects into one larger data collection and policy proposal. The Committee will determine next steps based on public comment feedback.

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) determined in a Federal Register notice that OPTN living donor guidelines should be given the same status of other OPTN policies.[102] In that notice, under 42 CFR 121.4(a)(6), the Secretary directed 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].[103] The Committee submits their project concepts under the authority of this Secretarial directive; and the National Organ Transplant Act (NOTA), which

[101] OPTN Living Donor Committee, *Meeting Summary,* May 18, 2021. Available at https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/.
[102] 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). https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-andtransplantationnetwork-optn-living-donor.
[103] Ibid.

requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[104] Further, 42 U.S.C. 273a authorizes HHS to establish and maintain mechanisms to evaluate the long-term effects associated with living donations. Federal regulations at 42 CFR 121.11 also authorize the OPTN and SRTR to collect information concerning living organ donors and prospective living organ donors as the Secretary deems appropriate.

The concepts outlined in this paper address living organ donors by suggesting options for 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. Additionally, the project would include review of OPTN living donor data collection forms to propose modifications in order to ensure accurate data collection on living donors and improve analyses to inform evidence-based policy making.

Conclusion

To support a collaborative approach to living donor data collection, the Committee proposes that, in accordance with the concepts outlined in this paper, the OPTN collect living donor candidate and donation decision data in an effort to support the Living Donor Collective as the national living donor registry performing long-term follow-up. With the implementation of these concepts, the Committee intends to increase efficiency, reduce redundancy, and acquire key data. The Committee seeks feedback on these concepts and opportunities to streamline living donor data collection efforts and support long-term follow-up of living donors.

Considerations for the Community

The Committee requests feedback on all aspects of this concept paper, including the following questions:

- What are living donors' preferences on how to engage with long-term follow-up?
- Is *living donor candidate* the correct term? Is the proposed definition appropriate?
- How do living donor programs define *evaluation*?
- What is the minimum amount of data necessary to collect on living donor candidates?
    - What are the specific necessary data elements?
    - What organ-specific clinical data are necessary for living donor candidates?
- What are the transplant communities' recommendations related to shifting 12- and 24- month follow-up from the OPTN to the Living Donor Collective?
- How do living donor programs recommend operationalizing data collection on living donor candidates and donation decision to reduce burden?
- What data do potential living donors need to inform decision-making and post-donation health care?
- What recommendations do transplant coordinators have on updates to OPTN living donor data collection forms?
    - What data elements and data definitions require modifications or deletions?
    - What data elements are missing from current OPTN living donor data collection forms?

[104] 42 USC § 274(b)(2)(I).

Appendix A: Pre-donation Data Elements Collected by the OPTN & SRTR

Additional information is found in the footnotes of this appendix.

Some data elements such as name, date of birth, social security number, etc. are automatically uploaded to the OPTN Living Donor Registration form from the OPTN Living Donor Feedback (Add Donor) form. Therefore, some of the overlap on the two OPTN data forms do not require duplicate data entry, it is automated. Additionally, not all data elements in the table are required data elements.

Data element	SRTR Initial Registration	OPTN Living Donor Feedback (Add Donor)[105]	OPTN Living Donor Registration[106]
Overview Information			
Donor Center	X	X	
Allow OPO to run match?		X	
Data of initial in-clinic screening for living donation	X		
SSN	X	X	X
Date of birth	X	X	X
Organ type	X	X	X
Relationship to recipient	X		X
Name	X	X	X
Address	X		X
Mailing Address same as Address?	X		
Primary Phone	X		X
Secondary Phone	X		
Primary Email	X		X
Secondary Email	X		
Preferred method of contact	X		
Other contact - Name	X		
Other contact - Address	X		
Other contact - Primary phone	X		
Other contact - Secondary phone	X		
Other contact - Email	X		

[105] The OPTN Living Donor Feedback (Add Donor) instrument also includes the data element, "*living donor recovery procedure aborted after non received anesthesia OR living donor organ recovered, but not transplant?".* This data element is excluded from the above table because it is a post-surgery event related data element. Additionally, *Allow OPO to run match* is the only data element that is not a request data element on this form.

[106] The OPTN Living Donor Registration instrument includes surgical and post-donation data elements. These data elements are excluded from the above table because the focus of the table is pre-donation related data elements. Additionally, all pre-donation related data elements on this form are required data entry.

Data element	SRTR Initial Registration	OPTN Living Donor Feedback (Add Donor)[105]	OPTN Living Donor Registration[106]
Overview Information			
Other contact - Relationship to donor candidate	X		
Demographic Information			
Sex	X	X	X
Marital Status	X		X
Ethnicity/Race	X	X	X
Citizenship	X		X
Health Insurance	X		X
Working for income	X		X
Is donation a financial hardship	X		
Highest Education Level			X
Functional Status			X
Physical Capacity			X
Pre-Donation Clinical Information			
Donor ABO		X	X
Donor histocompatibility		X	
History of cigarette use	X		X
Other tobacco or e-cigarette use	X		X
Marijuana use	X		
History of cancer	X		X
Diabetes	X		X
Cholesterol-lowering medication	X		
Hypertension[107]	X		
Height	X		X
Weight	X		X
Blood pressure[108]	X		
Total Cholesterol	X		
HDL cholesterol	X		
LDL cholesterol	X		

[107] Note that the SRTR Initial Registration instrument collects hypertension on all living donor candidates, while the OPTN Living Donor Registration collects history of hypertension only on living kidney donors. See footnote #33.

[108] Note that the SRTR Initial Registration instrument collects blood pressure on all living donor candidates, while the OPTN Living Donor Registration collects blood pressure measurements only on living kidney donors. See footnote #34.

Data element	SRTR Initial Registration	OPTN Living Donor Feedback (Add Donor)[105]	OPTN Living Donor Registration[106]
Overview Information			
Triglycerides	X		
Fasting blood glucose	X		
HIV/CMV/HBV/HCV/EBV Testing			X
Pre-Donation Liver Clinical Information			
Total Bilirubin	X		X
SGOT/AST	X		X
SGPT/ALT	X		X
Alkaline Phosphatase	X		X
Serum Albumin	X		X
Serum Creatinine	X		X
INR	X		X
Liver Biopsy	X		X
Platelet Count	X		
MRI obtained	X		
Hepatitis, jaundice, or abnormal liver tests	X		
Alcohol consumption over last 12 months	X		
Average alcohol consumption over last 12 months	X		
Pre-donation Kidney Clinical Information			
History of hypertension[109]			X
Serum Creatinine	X		X
Preoperative Blood Pressure[110]			
Urinalysis	X		X
Serum Uric Acid	X		
APOL1 risk	X		
Family history of CKD	X		
Gout	X		
Family history of diabetes	X		
Kidney stones	X		

[109] Note that the OPTN Living Donor Registration collects history of hypertension only on living kidney donors, while the SRTR Initial Registration instrument collects hypertension on all living donor candidates,. See footnote #31.
[110] Note that the OPTN Living Donor Registration collects blood pressure only on living kidney donors, while the SRTR Initial Registration instrument collects blood pressure on all living donor candidates,. See footnote #32.

Data element	SRTR Initial Registration	OPTN Living Donor Feedback (Add Donor)[105]	OPTN Living Donor Registration[106]
Overview Information			
Pregnancy (gestational diabetes/gestational hypertension/preeclampsia)	X		
Pre-donation Lung Clinical Information			
FVC % predicted			X
FEV1 % predicted			X
FEF (25-75%) % predicted			X
TLC % predicted			X
Diffusing lung capacity corrected for alveolar volume % predicted			X
PaO2 on room air			X
Pre-Donation Uterus Clinical Information[111]			
Human Papillomavirus (HPV) - cervical specimen only by DNA or mRNA			X
Herpes Simplex Virus (HSV) 1/2 (IgG)			X
Gonorrhea (NAT)			X
Chlamydia (NAT)			X
Vaginal Candidiasis (collected at the time of evaluation)			X
Vaginal Candidiasis (collected at the time of donation)			X
Bacterial Vaginosis (Gardnerella vaginalis)			X
Trichomoniasis			X
Other Testing			X
Uterine Imaging			X
Gravidity			X
Parity			X
Spontaneous Abortion			X
Induced Termination			X
Prior Full Term Live Births			X

[111] Data collection on living vascularized composite allograft (VCA) donors was approved by the OPTN Board of Directors on December 7, 2020, and pending implementation. The data elements indicated here are the pre-donation related data elements for living VCA donors that will be implemented. For more information, reference *Modify Data Collection on VCA Living Donors* briefing paper. Available at https://optn.transplant.hrsa.gov/media/4215/bp_dec-2020_modify-data-collection-on-vca-living-donors.pdf.

Appendix B: OPTN Data Elements Under Review

Living Donor Feedback (Add Donor)		
Section	**Data Elements**	**Recommendation**
Institution	Donor Workup Facility	Keep
Donor Information	Donor Name (Last, First, Middle)	Keep
Donor Information	Donor SSN	Keep
Donor Information	Donor date of birth	Keep
Donor Information	Donor race/ethnicity	Modify
Donor Information	Donor birth sex	Keep
Donor Information	Donor ABO	Keep
Donor Information	Allow OPO to run match	Keep
Donor Information	Donor histocompatibility	Keep
Donor Information	Living donor recovery procedure aborted after donor received anesthesia OR living donor organ recovered, but not transplanted?	Modify
Donor Information	Organ type	Modify
Donor Information	Is the donor participating in any KPD?	Modify

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Provider Information	Recipient center	Keep
Donor Information	Marital Status at Time of Donation	Delete
Donor Information	Social Support at Time of Donation	Add
Donor Information	Donor Type	Modify
Donor Information	Did the donor have health insurance	Keep
Donor Information	Functional Status	Remove
Donor Information	Physical Capacity	Remove
Donor Information	Working for Income	Keep
Donor Information	Donor Name	Keep
Donor Information	UNOS Donor ID #	Keep
Donor Information	Address	Keep
Donor Information	Home City	Keep
Donor Information	State	Keep
Donor Information	Zip Code	Keep (make required)
Donor Information	Home Phone	Pending Review
Donor Information	Work Phone	Pending Review
Donor Information	Email	Pending Review

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Donor Information	SSN	Keep
Donor Information	Date of Birth	Keep
Donor Information	Birth Sex	Keep
Donor Information	ABO Blood Group	Keep
Donor Information	Ethnicity/Race	Keep
Donor Information	Citizenship	Keep
Donor Information	Highest Education Level	Keep
Pre-Donation Clinical Information	History of Cancer/Cancer free interval	Modify
Pre-Donation Clinical Information	History of Cigarette Use	Modify
Pre-Donation Clinical Information	Other Tobacco Used	Modify
Pre-Donation Clinical Information	Diabetes / Treatment	Keep
Pre-Donation Clinical Information	Pre-Donation Height and Weight	Pending Review
Pre-Donation Clinical Information	Have any of the following viruses ever been tested for: HIV, CMV, HBV, HCV, EBV	Pending Review
Pre-Donation Clinical Information	HIV Status	Pending Review
Pre-Donation Clinical Information	CMV/Total/IgG/IgM/Nucleic Acid Testing	Pending Review
Pre-Donation Clinical Information	HBV/DNA (NAT/PCR)/Core Antibody/Surface Antigen	Pending Review
Pre-Donation Clinical Information	HCV/RNA (NAT/PCR)/Antibody/RIBA	Pending Review
Pre-Donation Clinical Information	EBV/Total/IgG/IgM	Pending Review
Pre-Donation Clinical Information	Vaccination Status	Pending Review
Pre-Donation Liver Clinical Information	Total Bilirubin	Pending Review
Pre-Donation Liver Clinical Information	SGOT/AST	Pending Review
Pre-Donation Liver Clinical Information	SGPT/ALT	Pending Review
Pre-Donation Liver Clinical Information	Alkaline Phosphatase	Pending Review
Pre-Donation Liver Clinical Information	Serum Albumin	Pending Review

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Pre-Donation Liver Clinical Information	Serum Creatinine	Pending Review
Pre-Donation Liver Clinical Information	INR	Pending Review
Pre-Donation Liver Clinical Information	Liver Biopsy/% Macro vesicular fat/% Micro vesicular fat	Pending Review
Pre-Donation Kidney Clinical Information	History of Hypertension	Modify
Pre-Donation Kidney Clinical Information	Serum Creatinine	Keep
Pre-Donation Kidney Clinical Information	Preoperative Blood Pressure Systolic	Pending Review
Pre-Donation Kidney Clinical Information	Preoperative Blood Pressure Diastolic	Pending Review
Pre-Donation Kidney Clinical Information	Urinalysis: Urine Protein/Protein-Creatinine Ratio	Modify
Pre-Donation Lung Clinical Information	FVC % predicted	Pending Review
Pre-Donation Lung Clinical Information	FEV1 % predicted	Pending Review
Pre-Donation Lung Clinical Information	FEF (25 - 75%) % predicted	Pending Review
Pre-Donation Lung Clinical Information	TLC % predicted	Pending Review
Pre-Donation Lung Clinical Information	Diffusing lung capacity corrected for alveolar volume % predicted	Pending Review
Pre-Donation Lung Clinical Information	PaO2 on room air	Pending Review
Liver Surgical Information	Type of Transplant Graft	Pending Review
Kidney Surgical Information	Type of Transplant Graft	Modify
Kidney Surgical Information	Intended Procedure Type	Modify
Kidney Surgical Information	Conversion from Laparoscopic to Open	Pending Review
Lung Surgical Information	Type of Transplant Graft	Pending Review

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Lung Surgical Information	Procedure Type	Pending Review
Lung Surgical Information	Conversion from Thoracoscopic to Open	Pending Review
Lung Surgical Information	Intra-Operative Complications	Pending Review
Post-Operative Information	Cause of Death	Modify
Post-Operative Information	Non-Autologous Blood Administration	Modify
Post-Operative Information	Date of Initial Discharge	Modify
Post-Operative Information	Donor Status	Keep
Post-Operative Information	Date Last Seen or Death	Modify
Post-Operative Information Section		Modify
Liver Related Post-Operative Complications	Biliary Complications	Pending Review
Liver Related Post-Operative Complications	Vascular Complications Requiring Intervention	Pending Review
Liver Related Post-Operative Complications	Other Complications Requiring Intervention	Pending Review
Liver Related Post-Operative Complications	Reoperation	Pending Review
Liver Related Post-Operative Complications	Any Readmission After Initial Discharge	Pending Review
Liver Related Post-Operative Complications	Other Interventional Procedures	Pending Review
Kidney Related Post-Operative Complications	Vascular Complications Requiring Intervention	Pending Review
Kidney Related Post-Operative Complications	Other Complications Requiring Intervention	Pending Review
Kidney Related Post-Operative Complications	Reoperation	Pending Review

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Kidney Related Post-Operative Complications	Any Readmission After Initial Discharge	Pending Review
Kidney Related Post-Operative Complications	Other Interventional Procedures	Pending Review
Lung Related Post-Operative Complications	Post-operative complications during the initial hospitalization	Pending Review
Lung Related Post-Operative Complications	Any Readmission After Initial Discharge	Pending Review
Post-Operative Clinical Information	Serum Creatinine	Pending Review
Post-Operative Clinical Information	Post-Op Blood Pressure Systolic	Pending Review
Post-Operative Clinical Information	Post-Op Blood Pressure Diastolic	Pending Review
Post-Operative Clinical Information	Urinalysis: Urine Protein/Protein-Creatinine Ratio	Pending Review
Post-Operative Clinical Information	Donor Developed Hypertension Requiring Medication	Pending Review
Post-Operative Clinical Information	Total Bilirubin	Pending Review
Post-Operative Clinical Information	SGOT/AST	Pending Review
Post-Operative Clinical Information	SGPT/ALT	Pending Review
Post-Operative Clinical Information	Alkaline Phosphatase	Pending Review
Post-Operative Clinical Information	Serum Albumin	Pending Review
Post-Operative Clinical Information	Serum Creatinine	Pending Review
Post-Operative Clinical Information	INR	Pending Review
Post-Operative Clinical Information	Most Recent Date of Tests	Pending Review
Post-Operative Clinical Information	Weight	Pending Review
Organ Recovery	Organ Recovery Date	Keep
Organ Recovery	Organ(s) Recovered	Keep

Living Donor Registration		
Section	**Data Elements**	**Recommendation**
Organ Recovery	Recipient Name (Last, First)	Keep
Organ Recovery	Recipient SSN#	Keep
Organ Recovery	Donor Recovery Facility	Keep
Organ Recovery	Donor Workup Facility	Keep

Living Donor Follow-up		
Section	**Data Elements**	**Recommendation**
Provider Information	Recipient center	Keep
Provider Information	Followup center	Keep
Donor Information	Name	Keep
Donor Information	Transplant Date	Keep
Donor Information	DOB	Keep
Donor Information	SSN	Keep
Donor Information	Gender	Keep
Donor Information	Donor ID	Keep
Donor Information	Recovery Date	Keep
Donor Information	Organ	Keep
Donor Status	Functional Status	Remove
Donor Status	Physical Capacity	Remove
Donor Status	Working for Income	Modify
Donor Status	Cause of Death	Modify
Donor Status	Date of last contact or death	Keep or modify
Donor Status	Most Recent Donor Status since	Modify
Donor Status	Attempts to Contact	Remove
Donor Status	Date of Initial Discharge	Modify
Donor Status	Loss of Insurance Due to Donation	Keep
Clinical Information	ER or urgent care visit related to donation since last follow-up	Pending Review
Clinical Information	Current Weight/Date	Pending Review
Liver Clinical Information	Total Bilirubin	Pending Review
Liver Clinical Information	SGOT/AST	Pending Review
Liver Clinical Information	SGPT/ALT	Pending Review
Liver Clinical Information	Alkaline Phosphatase	Pending Review
Liver Clinical Information	Serum Albumin	Pending Review
Liver Clinical Information	Serum Creatinine	Pending Review
Liver Clinical Information	INR	Pending Review
Liver Clinical Information	Platelet count	Pending Review

Living Donor Follow-up		
Section	**Data Elements**	**Recommendation**
Kidney Clinical Information	Diabetes / Treatment	Modify
Kidney Clinical Information	Serum Creatinine	Pending Review
Kidney Clinical Information	Blood Pressure Systolic	Pending Review
Kidney Clinical Information	Blood Pressure Diastolic	Pending Review
Kidney Clinical Information	Donor Developed Hypertension Requiring Medication	Pending Review
Kidney Clinical Information	Urinalysis: Urine Protein/Protein-Creatinine Ratio	Modify
Lung Clinical Information	Activity Level	Pending Review
Lung Clinical Information	Chronic Incisional Pain	Pending Review
Complications	Has the donor been readmitted since	Pending Review
Complications	Regularly administered dialysis as an ESRD patient	Modify
Complications	Kidney Complications since	Modify
Complications	Liver Complications since	Keep
Complications	Complications since	Keep