

**Guidance for Developing and Implementing Procedures to Collect Post-Donation  
Follow-up Data from Living Donors**

**Developed by the OPTN/UNOS Living Donor Committee**

**Purpose**

The Living Donor Committee developed this resource to help transplant programs maintain contact with living donors and collect follow-up data from them.

**Introduction**

In November 2009, the OPTN Board of Directors charged the Living Donor (LD) Committee with developing and disseminating a resource outlining best practices for collecting and submitting living donor follow-up data, based on a review of high-performing programs. To this end, the LD Committee developed a non-exhaustive set of recommendations to assist transplant programs to improve their protocols for maintaining contact with donors and for the collection and submission of complete and accurate Living Donor Follow-up (LDF) data. These recommendations derive directly and exclusively from actual practices employed by high-performing programs, as described further below.

Follow-up of living kidney and liver donors is crucial for understanding and minimizing the risks faced by donors. The OPTN currently requires transplant programs to report follow-up data on living donors at discharge (or 6 weeks post-donation, whichever is earlier), 6 months, 1 year, and 2 years after donation. Compliance with current OPTN data submission policies is high (i.e., transplant programs submit the required LDF forms). However, the LDF forms that are submitted often contain missing or incomplete data. Living donors may be lost to follow-up or transplant centers may have obtained only partial data on donors at the time of LDF form submission.

This resource does not specify official policy for clinical practice with respect to the follow-up medical care of living donors and it does not prescribe or define a standard of care. It does not carry any monitoring or enforcement implications associated with any OPTN/UNOS policy. It will not be used to determine member compliance with any policy or bylaw. Rather, this resource is intended for transplant centers' voluntary use. It is intended to help programs to review, discuss, and generate ideas on how best to develop or improve their own strategies to promote optimal follow-up of living donors. Transplant programs should consider the recommendations below as suggestions, and consider the extent to which each suggestion may or may not be applicable or feasible given their own institutional setting and operational constraints.

Both new and existing living donor transplant centers can use this resource as a “toolbox” when developing or modifying their living donor follow-up protocols. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

### **Methodology for generating recommendations**

Two strategies were employed to generate recommendations. First, members of the LD committee interviewed UNOS transplant program auditors in order to learn about auditors’ observations of factors contributing to programs’ ability to maintain contact with donors and obtain follow-up data. The auditors were interviewed as a group after they had visited the first 10 living donor transplant programs audited in 2010. They were asked not to identify specific programs but to focus on their general observations instead.

Second, LD committee members, working with OPTN/UNOS staff, identified and interviewed representatives from a total of 8 transplant programs (6 living kidney donor programs, 2 living liver donor programs). These programs were selected because they were not only compliant in submitting LDF forms but had rates of complete donor follow-up information on donor status (alive/deceased) and donor lab values in greater than 80% of their donors. These statistics were based on living donations during the period 3/1/08 – 2/28/09. One to three individuals from each center (designated by their program directors and administrators as having the greatest knowledge of the follow-up procedures in use at their centers) participated together in a single telephone interview (one call per center). Members of the LD committee, including living donors, conducted the interviews. During these open-ended, qualitative interviews, respondents were asked to describe the procedures used by the centers for following living donors, what strategies appeared to be most effective, what strategies (if any) had been discarded because of ineffectiveness, what barriers were faced in following living donors, which personnel recorded and submitted data to the OPTN, and any quality assurance or quality improvement activities undertaken with regard to living donor follow-up. Information collected during the interviews was, in many cases, separately corroborated by program directors and/or administrators via email correspondence.

The decision to interview representatives from 8 programs (rather than from a smaller or greater number of programs) was based on key principles of qualitative methodology. Namely, an iterative approach was employed such that interviews continued until no new themes or major strategies emerged that had not been discussed in earlier interviews.

### **Recommendations**

Three categories of “best practice” factors emerged. Thus, although the specific strategies utilized by any given program vary, high-performing programs each have developed core activities that reflect:

- (1) the conviction that donor follow-up is essential for donor safety and well-being,
- (2) the importance of building and maintaining a relationship with each donor,
- (3) the use of a systematic approach to follow-up, with ongoing quality assurance activities.

Within each of these three categories, we list below recommendations based on the strategies used by programs to maintain contact and collect complete and accurate follow-up data from donors. No single program employs all of the strategies described. No recommendation is listed unless it is employed by one or more programs.

1. Program “culture” focused on safety and positive donor outcomes: Develop and promote a program “culture” or philosophy that emphasizes the importance of donor follow-up in order to ensure donor safety and well-being. View donor follow-up as critical for monitoring donor outcomes and well-being. If an increase in program volume/size is an aim, work to actively promote positive donor outcomes so that growth can occur in an atmosphere of safety.
  - Keep the emphasis of program activities focused on the donor as the patient, separate from the transplant recipient.
    - If donors are typically seen in clinic by the program for LDF data collection and clinical evaluation (as opposed to visiting a primary care physician (PCP) for these purposes), consider establishing a dedicated post-donation clinic to see donors after surgery and obtain follow-up information. Separate this activity from recipient follow-up in order to reflect a program philosophy focused on the donor.
    - Rather than interspersing donor care guidelines and standards among program policy and protocols for transplantation in general, consider maintaining donor policy and protocols separately. This separation allows for more complete consideration of donor-specific issues.
  - Work to develop strong staff commitment to donor follow-up and staff accountability for collecting complete follow-up data. Show that expectations regarding complete and accurate follow-up data come from the top down: the program directors and administrators expect a commitment to follow-up from both staff and donors.
  - Strive for high follow-up rates: establish specific follow-up target levels. It is not unrealistic to set the target at 100% complete donor follow-up through at least the first two years post-donation.
    - Consider whether it is possible to dedicate certain staff members to providing follow-up care and completing donor LDF forms; these staff members would focus on donors and have little to no responsibility for following or completing forms on transplant recipients.

- When program expectations for complete donor follow-up rates are not met, review and consider revisions to program procedures in order to increase follow-up rates (See Section 3 [Systematic approach] below for additional details).
  - If any donor is to be listed as “lost to follow-up” on the LDF forms, consider having a program requirement that this entry be approved by the program coordinator, administrator, or another responsible party (indicating that all options for locating the donor have been exhausted) before the LDF forms are submitted.
- Work to ensure that donors understand and are committed to the need for follow-up.
    - From the beginning of the donation process, inform prospective donors of the importance of follow-up and the specific post-donation follow-up time points. Ensure that they are informed not only by the living donor coordinator but by other health care professionals seen during the course of the education and evaluation process (e.g., surgeon, nephrologist/hepatologist, social worker, independent donor advocate).
    - Present information about the follow-up time points in multiple formats, e.g., orally, visually (on DVD) and in printed and electronic educational materials. List the specific time points for follow-up in the informed consent form that the donor must sign before donation. Remind the donor of the follow-up time points before hospital discharge after surgery.
    - In order to increase donors’ own commitment to a healthy lifestyle post-donation, ask donors to acknowledge verbally and in writing that they understand the need for follow-up, as well as their responsibility (if any) for costs associated with any follow-up evaluation or care. (As noted below, consider whether the program will cover some or all follow-up costs.)
    - Consider whether to ask prospective donors to acknowledge and sign a care plan which includes the name of the PCP who will provide long-term care after donation and indicates that they understand the importance of obtaining regular health maintenance care from a PCP. Obtain these signed documents separately from the signed informed consent form and view them as part of the donor education process.
    - Consider whether to request that prospective donors have a standard physical examination from their PCP close to the time of donors’ pre-donation evaluation. One purpose of this request is work

toward ensuring that donors have established a relationship with a PCP so that post-donation follow-up care is more likely.

- Develop a process to educate the donor's PCP on the risks of living donation, the need for follow-up, the time points for required follow-up data collection, the tests recommended at follow-up visits, and how often continued follow-up beyond two years might be advisable. Establish open lines of communication.
  - After the donation surgery, send a discharge summary to the PCP (with the donor's permission) along with a letter that explains donor needs for long-term health maintenance.
  - If the donor will be visiting the PCP rather than the program for LDF data collection during the first two years post-donation, send a letter before each PCP visit (with the donor's permission) delineating exactly what data will need to be collected and why.
  - Update the donor's PCP regarding the results of any additional tests or procedures undertaken by the program.
- Collect donor follow-up data not only in order to comply with OPTN/UNOS data submission requirements but also to monitor donor health and keep the donor's regular health care provider informed.
  - Establish procedures to review any abnormal or anomalous finding obtained during LDF data collection, as well as procedures for obtaining additional tests and care as needed.
  - After a given follow-up assessment, inform donors (by telephone, letter, or email) about the outcomes of any standard tests or additional tests/procedures recommended.
- Beyond OPTN/UNOS requirements to collect specific donor follow-up information through 2 years post-donation, consider whether the transplant program wishes to collect additional donor outcomes data, either during the first two years post-donation and/or beyond the first two years. Decide whether such data would help to address program priorities or interests (with approvals of Quality Improvement or Institutional Review Boards as appropriate), or whether the collection of such data would reflect a programmatic view that donor follow-up should be for life. Similarly, consider whether to participate in other local or national work focused on donor outcome issues. Examples of donor outcomes data collection and clinical activities (beyond the data required for LDF forms) could include:

- Administration of surveys designed by program staff to assess donors’ quality of life and general well-being. These surveys may continue to be administered beyond 2 years post-donation.
- Continued annual collection of laboratory and other clinical data values to monitor organ function and donor health beyond 2 years post-donation.
- Participation in national initiatives to survey donor well-being.
- Develop and implement strategies to minimize any burden on donors related to the collection of follow-up data.
  - Develop systematic plans for how LDF data will be collected from donors who are unable to or choose not to return to the program for follow-up (See Section 3 [Systematic approach] below for additional details).
  - If the program views PCP follow-up as a more appropriate and less burdensome option than returning to the program for LDF data collection and clinical care (e.g., due to a decision that this approach is best for fostering continuity of long-term care for the donor), develop a systematic plan for alerting the PCP about what information is needed, and coordinate with the PCP regarding the communication process for reporting clinical and laboratory findings to the program.
  - Consider having the program cover some or all of the dollar costs of required follow-up data collection during the first 2 years post-donation (e.g., costs of medical evaluation at follow-up time points; costs of lab work). Consider providing cost coverage during either a portion of the first two years post-donation (e.g., first six months or during the first year) or during the entire 2-year period.
  - Consider whether cost coverage would be possible for follow-up clinic visits completed by program personnel and/or whether cost coverage could extend to PCP visits devoted to follow-up data collection.
  - Consider whether cost coverage will be provided for any care required in the event that abnormal findings related to the living donation emerge during follow-up clinic or PCP visits.
  - Consider whether cost coverage could extend to any living donation-related medications prescribed at discharge.

- If the program covers the cost of donation-related required lab tests, arrange for bills for lab work to be sent directly to the program, or consider contracting with a national facility in advance to provide services to all donors. Under this approach, requisitions may be sent directly to the lab via email or secure web portals and, after a donor has had the required tests completed, the results are sent automatically to the program
- If cost coverage will be provided for follow-up visits conducted by a PCP, notify the donor’s PCP about what services are billable and how to bill the program for services.
- If donors develop financial problems after donation (including the loss of health insurance or inability to afford copayments), work with the donor to identify sources of coverage for donor follow-up costs or consider whether the program can cover living donation-related costs.

2. Relationship Building: Use a variety of “relationship building” strategies to maintain contact with donors and foster high rates of donor follow-up. Consider whether any of the following would be helpful:

- Use a dedicated living donor coordinator or other clinician (e.g., a social worker) who talks with the prospective donor when they first have contact with the program, sees them during the evaluation process, and who continues to maintain contact with them, including seeing them for clinic visits post-donation.
- If it is not possible for the same donor coordinator (or other dedicated clinician) to follow donors both before and after donation, assign a single post-donation donor coordinator to consistently contact donors and collect LDF data so that they can form a steady relationship.
- Have the donor coordinator (or other dedicated clinician) serve as the point of contact for all post-donation clinical and follow-up visit scheduling issues. The coordinator/clinician may see the donor for face-to-face follow-up visits at the medical center or contact the donor and the donor’s PCP if the PCP will be collecting the follow-up data.
- At follow-up time points, if the program holds a single clinic to see both donors and recipients, consider scheduling donor follow-up visits to coincide with recipient follow-up visits (in situations where donors and recipients know each other). This builds on the relationship between these individual and emphasizes the need to consider each person’s health and well-being.

- Use the LDF data collection clinic visit or any telephone contact not only as an opportunity to obtain the required follow-up information (or arrange for it to be collected) but to further build a relationship with the donor. Use the contact as an opportunity to ask the donor general questions about his/her health and well-being in order to identify any issues or concerns that may need to be addressed, as well as to solicit comments about aspects of the donation process that might be improved. Provide referrals as needed.
  - Use a dedicated clinician rather than a non-clinician (e.g., data manager or clerk) to obtain or record follow-up data. Non-clinicians (a) are unlikely to have had any prior relationship with the donor, (b) would not be able to advise the donor regarding any questions that might arise regarding the follow-up information collected, (c) would not necessarily recognize test values that were abnormal or likely to be in error.
  - Work actively to build and maintain relationships with donors' PCPs. This helps to ensure that the PCPs understand the kind of follow-up that donors need and that PCPs (if they are involved in collecting any required follow-up data) understand why the information is required for donor care. Provide the PCP with contact information for the program in case the PCP has questions about clinical or lab results.
3. Systematic approach to follow-up with regular review of LDF rates: Develop and periodically reassess the effectiveness of a systematic, methodical approach to donor follow-up. Incorporate quality assurance and improvement strategies in order to strive for 100% ascertainment of LDF data. Realize that no single approach is necessarily best; the most important principle is to develop procedures that can be followed reliably. Be open to modifications as needed.
- Be clear within the program and in communicating with donors as to which strategy the program prefers for the collection of LDF data and donor clinical care. Options include, for example: (a) a program preference for the donor to return to the program for face-to-face visits for every LDF time point, (b) a program preference for donors to be followed by their PCPs, (c) a decision to leave the location of follow-up to donor preferences. Clarification of program preferences can guide the implementation of strategies to ensure that LDF time points are not missed.
  - Develop specific plans for collecting LDF data based on the above preferences.
    - If the goal is for donors to return to the program for some or all visits, develop strategies to maximize the chances that visits will be completed. For example, at the time of hospital discharge after surgery, schedule the donor's initial follow-up visit. At the time of each visit, confirm and/or schedule the next visit.

- If the goal is for donors to be seen by their PCP for some or all visits beyond the post-surgical check-up, make sure that the PCP receives information at the time of the donor’s hospital discharge regarding the required visit schedule, what information is to be collected and forwarded to the Program, etc. (see also Section 1 [Program culture] above).
- If the goal is to support donor preferences for location of follow-up care, coordinate with the donor well ahead of each required visit regarding whether the donor will return to the program or see their PCP.
- Discuss with the donor before donation whether and which follow-up donation-related care costs will be covered by the program and for how long post-donation the costs will be covered (see also Section 1 [Program culture] above).
- Develop a range of strategies for relocating and re-contacting donors for routine reminders or other purposes.
  - Use not only regular mail and telephone contacts but email and even texting in order to communicate with donors. Consider emailing orders for lab work or other required tests by attaching PDFs.
  - Use internet search strategies to locate difficult-to-find donors.
  - Ask the donor before hospital discharge whether there is a family member who could be contacted in order to locate the donor in the event that donor contact information becomes outdated.
  - Ensure at hospital discharge that the donor has correct contact information for program staff responsible for follow-up care and/or available to address donor concerns and questions. Ask the donor to inform them if the donor’s contact information changes.
  - Send email reminders before the donor’s scheduled follow-up appointments with either the program or the donor’s PCP, and/or send reminders that program staff will be calling them to schedule appointments (or ensure the donor schedules them him/herself).
  - Routinely review and update contact information from donors each time they are successfully contacted post-donation, including telephone numbers, email addresses, and alternative contact information (e.g., another family member).

- Develop a system for tracking and generating reminders regarding donor follow-up data collection activities.
  - Use electronic reminders to alert the donor coordinator (or other dedicated clinician) about which donors will need LDF data collected in the near future. Program data management personnel may provide these automated reminders, or the donor coordinator may use electronic resources such as an Outlook calendar.
  - Use similar electronic approaches for reminders about what LDF forms are due for submission.
  - Use similar electronic reminders to indicate which donors have completed their follow-up visits and now need to be contacted with routine feedback regarding visit results (e.g., indicating that they are doing well, or indicating that they need additional tests or procedures).
  - Use similar electronic reminders to indicate which donors need to be contacted again to determine whether they completed any additional tests or procedures that had been ordered based on results from their follow-up visits.
  - Consider using an electronic spreadsheet to provide a complete summary of which donors are due for what types of contact/re-contact or for the completion of follow-up visits or other assessments.
  - Designate a day and time of the week or month (depending on program size) to review the complete list of which donors need to be contacted regarding the scheduling/rescheduling/reminders of follow-up data collection appointments.
- Develop a system for recording the medical information that is collected during follow-up care and for completing LDF forms.
  - Consider whether it would be helpful to design an assessment guide or tool to be used to ensure that all elements required on LDF forms are assessed during a given follow-up visit. Use this tool at clinic visits held by the program or mail it to the PCP before the donor's scheduled follow-up visits. Retain it as a source document and enter the information into the donor's medical chart/electronic medical record.

- Require that the individual who sees the donor for follow-up or who obtains the follow-up information from the PCP records the information obtained directly into the donor’s medical record. This ensures permanent documentation (as opposed to entering the data only onto LDF forms with no permanent documentation).
  - Develop specific procedures for recording follow-up information on the LDF forms for required submissions. Decide whether the individual responsible for collecting follow-up information will also record the information on the forms, or whether a data manager or clerk would extract the information from the medical record.
  - If a data manager or clerk extracts information for the LDF forms from the medical record, develop a protocol to train this individual in how to identify the correct data and what steps to take regarding values that appear unusual or out of range. For example, consider whether some of all completed LDF forms require review by the donor coordinator before submission.
  - Avoid using a system in which a data manager or clerk extracts the LDF information and records it on the forms without supervision and clinical review by a donor coordinator/clinician dedicated to the collection of follow-up information.
- Design and implement a protocol for quality assurance/quality improvement (QA/QI) for follow-up visit data and LDF form completion.
    - Develop a plan to routinely review a sample of submitted LDF forms, and compare these form to data in the donor’s medical record and other source documents in order to identify discrepancies. Decide how often the reviews should occur (e.g., monthly, quarterly).
    - Monitor the extent of missing data on submitted forms and develop a plan to reduce missing data rates.
    - Ensure that the individual conducting the QA review is trained in required procedures and is also able to identify unusual or out of range values for data.
    - Develop a plan for regularly reporting the results of QA monitoring with program members at program-wide meetings.
    - Investigate whether there is institutional support and resources for conducting QA/QI work.

- Encourage program staff to develop QI initiatives focused on donor outcomes and donor satisfaction. Use results to modify program activities and donor care and follow-up strategies.
- Consider developing a QA “scorecard” with various metrics to monitor program success, including LDF data collection rates. Work toward achieving specific scorecard targets and include scorecard information when reporting on program achievements to hospital senior management.

## **Acknowledgements**

The following Living Donor Programs assisted the LD Committee with the development of this document. The Program members named provided the greatest amount of information; Program directors and additional Program administrators also contributed to this document.

### Living donor liver programs

Lahey Clinic Medical Center, Burlington, MA (Denise Morin, RN, MSN)

University of Virginia Health Sciences Center, Charlottesville, VA (Anita Sites, RN, BSN, CCTC)

### Living donor kidney programs

The Christ Hospital, Cincinnati, OH (Barbara Groene, RN, BSN)

Mayo Clinic, Jacksonville, FL (Sharon White, RN, BSN, CCTC)

North Austin Medical Center, Austin, TX (James Pittman, RN, BSN)

Ohio State University Medical Center, Columbus, OH (Laura Murdock, MHA, Robin Petersen-Webster, LPN, CCTC)

Presbyterian-St. Luke's Medical Center, Denver, CO (Kelli Jantz, RN, Marita Dougherty, MSW)

University of North Carolina Hospitals, Chapel Hill, NC (Lauren Kearns, MSN, RN-BC, Ann Litts, RN, BSN, CCTC, Deborah Erickson, RN, BSN, MS, PhD)