

## **LIVING KIDNEY DONOR CONSENT** **Miami Transplant Institute**

Welcome to the Live Kidney Donor Program at the University of Miami Transplant Institute/Jackson Health System. Our program has had the wonderful opportunity of saving lives through live kidney donation for more than thirty years. Congratulations on your decision to be evaluated as a potential kidney donor. This is a valuable and rewarding experience. Your decision to donate should be voluntary and free from inducement or coercion. (Federal law related to the selling of organs: **The sale or purchase of human organs is a federal crime punishable to the full extent of the law. It is illegal to buy or sell any organs in the United States of America.**)

The evaluation for living donation requires tests to ensure you are healthy and safe. You will have **ample time during this process to reflect on your decision to donate.**

Specific outcome requirements must be met by the transplant center for Medicare certification and we are required to let you know if we do not meet those standards. **The University of Miami / Jackson Memorial Hospital meets all of the outcome requirements for transplant centers. Jackson Memorial Hospital is an approved Medicare facility for transplantation.**

Live kidney donor transplants are known to have the best long-term success rates, lower rates of rejection and markedly reduced waiting times for patients. A living donor has the unique opportunity to save and improve the quality of life of a transplant recipient. Live kidney donation can be very rewarding for both the donor and the recipient.

Donation of a kidney will not change your life expectancy nor increase your chance of kidney failure. After you recover from surgery, you can continue to live a healthy, active lifestyle. You do not need to modify your diet, exercise or activities. There is no evidence that donation will affect your ability to have children. Kidney donation offers no medical benefit to you. Therefore, it is important that you carefully consider your choice to donate. Please discuss your decision openly with your family and loved ones.

If you decide to proceed, our Live Kidney Donor team will prepare you medically and emotionally for surgery. You will not incur any financial responsibility for any testing ordered by the donor team during the work-up. Donor testing, surgery and post-operative care are covered under the Kidney Acquisition Act or the recipient's insurance company. No charge is made to the donor's insurance. Donors may also qualify for extra funding through the National Donor Assistance Program for travel, food and housing.

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**Our dedicated multi-disciplinary donor advocate team** is designed to help walk you safely through the donation process. This team is separate from the recipient team in order to ensure a confidential, objective evaluation and therefore serve your best interests. Once you have been selected as the primary donor to enter into the second phase of testing, you will meet with several members of our **Living Donor Team** that include the following:

- A **Living Donor Advocate** is a nurse that has your medical, emotional and psychosocial status as the top priority during the donation process. She will advocate for your preparedness and safety to undergo the donation surgery. She will focus only on objective data to serve your best interest as it relates to the donation process. She will have no connection with the recipient's medical care or decision-making. She can help you to understand and make the best voluntary informed decisions.
- A **Nephrologist** is a physician who specializes in kidney disease. The nephrologists will assist the donor team to determine if you are medically suitable for kidney donation. They will discuss the risks and benefits related to kidney donation. This includes potential medical and financial risks. The nephrologist will also discuss living versus deceased kidney transplant options and outcomes.
- A **Donor Surgeon** will meet with you to discuss the appropriateness of donation based on the information obtained during the evaluation process, only after you are determined to be medically suitable for donation. The surgeon will discuss the risks and benefits of undergoing kidney donation, the surgical approach based on the CT scan results, the risks and possible complications of surgery. The surgeon will also discuss living versus deceased kidney transplant options and outcomes.
- A **Psychologist/Social Worker** will meet with you to evaluate your ability to cope with the stress of donation and the post donation treatment plan. The evaluation will include a complete psychosocial assessment. The psychologist/social worker will help to identify your support persons and emotional preparedness and willingness to donate.
- A **Secretary** will schedule your diagnostic tests, consults and physician appointments. It is important to attend the scheduled appointments as directed.
- A **Registered Dietitian** is available to perform nutritional assessments and provide nutrition education if warranted.
- Patients may be referred to additional team members based on medical history and need.

You will be assigned to one of our support staff for initial screening and testing. They will coordinate your smooth journey through the donation process. Our nephrologist will then conduct a complete medical evaluation. You will also undergo a Psychological/Social evaluation. Our donor surgeon will then finalize the surgical approach and discuss the risks of surgery.

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**Phase I of the Donor Evaluation Process** consists of an initial 20-minute screening questionnaire (by phone or in person) to assess your past medical, surgical, social and family history. Donors may be excluded if they have high blood pressure, diabetes, cancer, heart disease, infections or kidney disease. Donors should be healthy individuals between the ages of 18 and 65 years. Donors must be mentally and emotionally capable of making the informed decision process to donate. They must be an appropriate blood type to donate. We will screen up to three potential donors for each recipient at a time.

Based on the medical screen, we will then determine whether you are a candidate to proceed with further testing. Suitable candidates will proceed with blood tests to identify your blood type, genetic tissue type and crossmatch.

We use these blood tests along with your medical history to determine which candidate is the "best match" for the recipient. You will be notified by our donor team as to whether you have been chosen as the "best match" to enter Phase II of the donor evaluation. You will be asked whether you wish to proceed with further workup for kidney donation.

Your complete medical work-up is confidential and will not be shared with the recipient. **If at any time during the process you should decide not to donate, simply notify us.** The donor team will give you a **confidential "opt-out"**, no questions asked without consequences. Our team will then inform the recipient for you. Your medical evaluation will remain confidential at all times.

We can then pursue other possible live donors.

**Alternative Treatments for the Recipient**

Alternative treatments or therapies may be available for the recipient's medical condition. They may decide to continue on hemodialysis or peritoneal dialysis instead of transplantation. You will have the opportunity to discuss this with the physician at the outpatient visits.

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## **POTENTIAL KIDNEY DONOR CANDIDATE**

**Phase II Evaluation:** Thank you for your interest in being a potential kidney donor and welcome to the second phase of your evaluation. All your information is held private and will not be shared with anyone including the recipient and family. Similarly, privacy laws prohibit us from sharing the recipient's medical information with you.

**Phase II** of your testing is designed to further determine your medical and psychological candidacy as a live kidney donor. This process can generally be completed within two to three working days. You will attend a group educational class to explain the donation process. In addition, our medical nephrologist and team will independently discuss the risks, benefits and alternatives with you.

Your testing will include the following routine tests/evaluation:

- 1. History and physical exam by a medical nephrologist or surgeon**
- 2. Lab (blood) tests**
- 3. Urine sample for evaluation**
- 4. Stool sample for evaluation**
- 5. Quantiferon Gold Test (Tuberculosis blood test)**
- 6. Chest x-ray and abdominal film**
- 7. EKG**
- 8. Mammogram (women > 40y, strong family history or breast mass)**
- 9. Gynecological exam (Pap smear/pelvic) - all females**
- 10. Psychological/Social evaluation**
- 11. Spiral CT scan**

You may be required to complete further evaluation (diagnostic tests, specialty medical consultation or laboratory studies) depending on your age, underlying health status and/or test results. Additional evaluation, if required, will obviously extend the process.

Sometimes final reports of these tests take up to two weeks to be returned to us for review.

The CT scan gives the surgeon valuable information about the anatomy of your kidneys and other intra-abdominal organs. The team uses this information to decide whether your kidney is suitable for donation. The surgeon will then plan the optimal surgical approach based on information gathered from this scan.

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## **Potential Kidney Donor Candidate**

### **Phase III**

#### **Scheduling your surgery:**

Once the donor surgeon has reviewed your medical work-up and the spiral CT scan and determined that no further testing is required, we will schedule your surgery. We will need to work with the recipient coordinator to find the next available, mutually acceptable date for both you and your recipient.

Once a date for surgery has been agreed upon, we will schedule you for **PHASE III (the Final Phase of the donor evaluation)**.

This includes the following evaluations:

- 1. Final Medical Clearance (with nephrologist)**
- 2. Surgical Clearance (with donor surgeon)**
- 3. Anesthesia Clearance (pre-operative evaluation).** This will include **any updating any labs (blood, urine, crossmatch) and/or diagnostic testing (Chest x-ray and EKG) required.**

Occasionally, during testing and even in the final phases of evaluation, we diagnose an underlying medical condition which may disqualify you as a donor. If this should occur, we will notify you and provide you with a letter and a copy of your medical records. You will then need to follow up with your primary care physician for further evaluation and potential treatment.

If you are unable to be a live kidney donor due to an underlying medical issue, your own medical insurance will need to cover these expenses.

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## **Potential Kidney Donor Candidate**

### **The Donor Surgery:**

You will be scheduled for surgery, and you will have a surgical evaluation to discuss the details of the operation, hospital course and post-operative care plan. During this visit, your surgeon will discuss the surgical risks of donation and obtain informed consent.

After a donation surgery, health insurance companies may consider the procedure a pre-existing condition and refuse payment for medical care, treatment or procedures. After the surgery, your health and life insurance premiums may increase. In the future they may refuse to insure you.

Specific medical, psychological, and financial risks associated with being a living donor, include, but may not be limited to the following:

#### **i. Potential Medical Risks**

- potential for surgical complications as outlined
- potential for organ failure and the need for a future organ transplant for the donor
- potential for other medical complications including long-term complications currently unforeseen
- increased risk with the use of over-the-counter medications and supplements such as Motrin, ibuprofen, non-steroidal anti-inflammatory medications

#### **ii. Potential Psychological Risks**

- potential for problems with body image
- possibility of post surgery adjustment problems
- possibility of transplant recipient rejection or non-function and need for re-transplantation
- possibility that the transplant recipient will have a recurrence of disease or other medical complications
- possibility of transplant recipient death
- potential impact of donation on the donor's lifestyle

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### iii. Potential Financial Risks

- personal expenses of travel, housing, child care and lost wages related to live donation are not reimbursed. In certain cases, living donors may qualify to be reimbursed for limited travel expenses, housing and meals and may receive financial assistance through **The National Living Donor Assistance Center**. Please ask the donor team for referral information. Your donation may qualify for a leave of absence from work under the *Florida Medical Leave Act*. Please check with the Human Resources representative at your job for additional information.
- possible loss of employment (e.g., military, firefighters, police)
- or the ability to obtain future employment
- potential impact on the ability to obtain or afford health, disability, and life insurance
- health problems experienced by living donors following donation are not covered by the recipient's insurance or the kidney acquisition fund

In certain cases, living donors may qualify to be reimbursed for limited travel expenses and may receive subsistence assistance.

The **Surgical Risks of Live Kidney Donation** are usually rare (1-2%) and are mostly small and manageable. Some of the most common risks are as follows:

Scars: You will have a scar from the surgery. This usually fades over time.

Pain and nausea: We will prescribe medication for you to take while recovering from surgery. Pain usually resolves as you heal.

Infection: Wound infection is the most common. This is usually managed with local wound care and antibiotics. To prevent urinary infections we will remove the catheter in your urinary bladder on the first post-operative day.

Pneumonias are a risk after anesthesia: In the hospital, you will be given an incentive spirometer for breathing exercises. You will be asked to cough and deep breathe regularly and engage in activity as soon as you can.

Blood Clots are a risk of any major surgery. A clot can travel to the lungs and cause a pulmonary embolus. We utilize sequential compression stockings during the surgery and hospitalization to help prevent this. You will be encouraged to sit in a chair on the first evening after surgery and you may walk as tolerated.

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Collapsed lung occurs when the chest cavity (space around the lung) is inadvertently opened during surgery. This may occur in mobilization of the kidney away from the chest cavity. Sometimes it is necessary to insert a tube into the chest to re-expand the lung.

Allergic reactions to medications or anesthesia: These are usually diagnosed early and corrective actions taken to reverse them.

Injury to surrounding intra-abdominal structures during kidney retrieval may occur while placing instruments in the abdominal wall or during dissection. These are usually recognized immediately and repaired during the operation.

Wound hernias occur infrequently. To help prevent hernia, you should not lift more than 20 pounds for six to eight weeks after surgery.

Bleeding is very rare. It is usually identified during the operation and immediate steps are taken to stop it. Sometimes, it requires conversion of a laparoscopic retrieval to an open retrieval. It rarely requires a blood transfusion. In the event that a transfusion is necessary, we will have blood available at the time of operation. Post-operative bleeding usually requires re-operation.

Death is exceedingly rare. Most studies estimate the risk at 0.03 to 0.06% (an average of 4 deaths for every 10,000 procedures). Thus donor nephrectomy carries a lower risk than getting hit by a bus or driving on a highway every day to work.

Abdominal or bowel symptoms such as bloating and nausea are common immediately after surgery and usually resolve.

On rare occasion there may be a delay in the immediate functioning or some dysfunction of the donor kidney after transplant to the recipient. The most common reasons for this are unique to the recipient, and may be immunological. In the event of an unsuccessful transplant you should rest assured that you did your very best to help your loved one.

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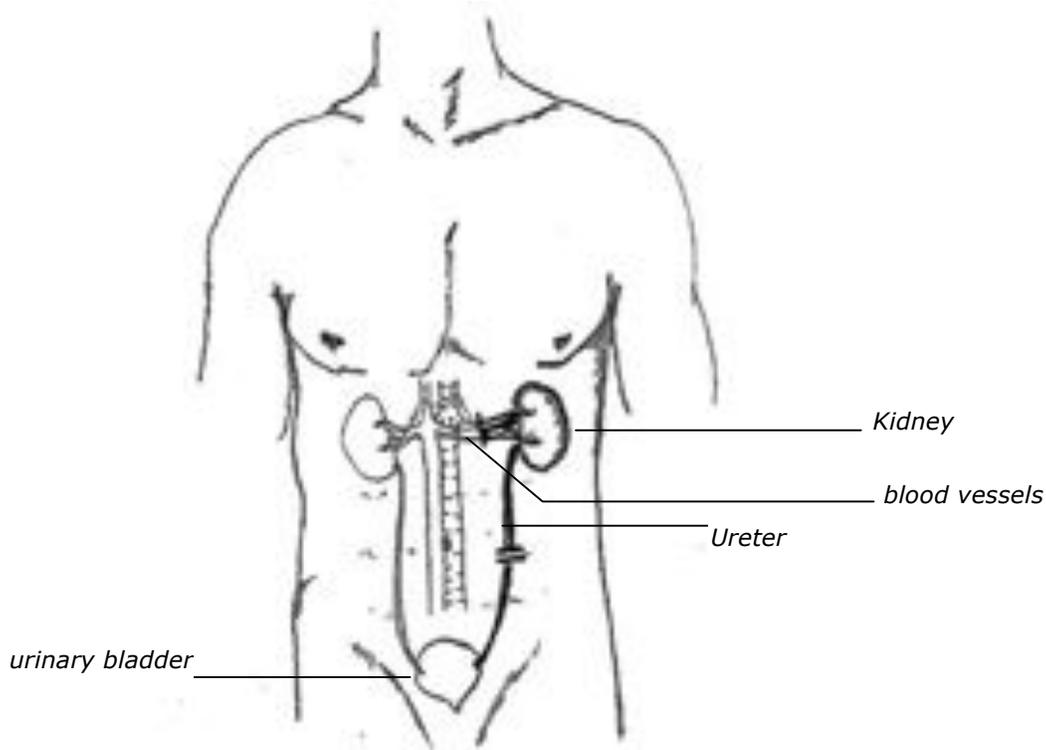
**Transplant Survival Data:**

Transplant Centers are required to report living donor follow-up information for at least 2 years after donation to the United Network of Organ Sharing. This information is available for your review online at the Scientific Registry of Transplant Recipients ([www.ustransplant.org](http://www.ustransplant.org)).

The national average for kidney transplant graft survival at one month post surgery is 96.96%, at one (1) year 91.72% and at three (3) years 81.14%. **The graft survival at the University of Miami / Jackson Memorial Hospital is above the expected survival rate at all three time periods.** The one-month survival is 98.89%, one (1) year 92.47% and three (3) years 86.83%. Graft survival is dependent on various factors and each patient's results are individualized.

**The Kidney Donor Operation (Nephrectomy)**

Nephrectomy involves dividing the blood vessels which supply the kidney (the renal artery and renal vein). The ureter which drains urine to the bladder is also divided. Some people may have multiple blood vessels or ureters.



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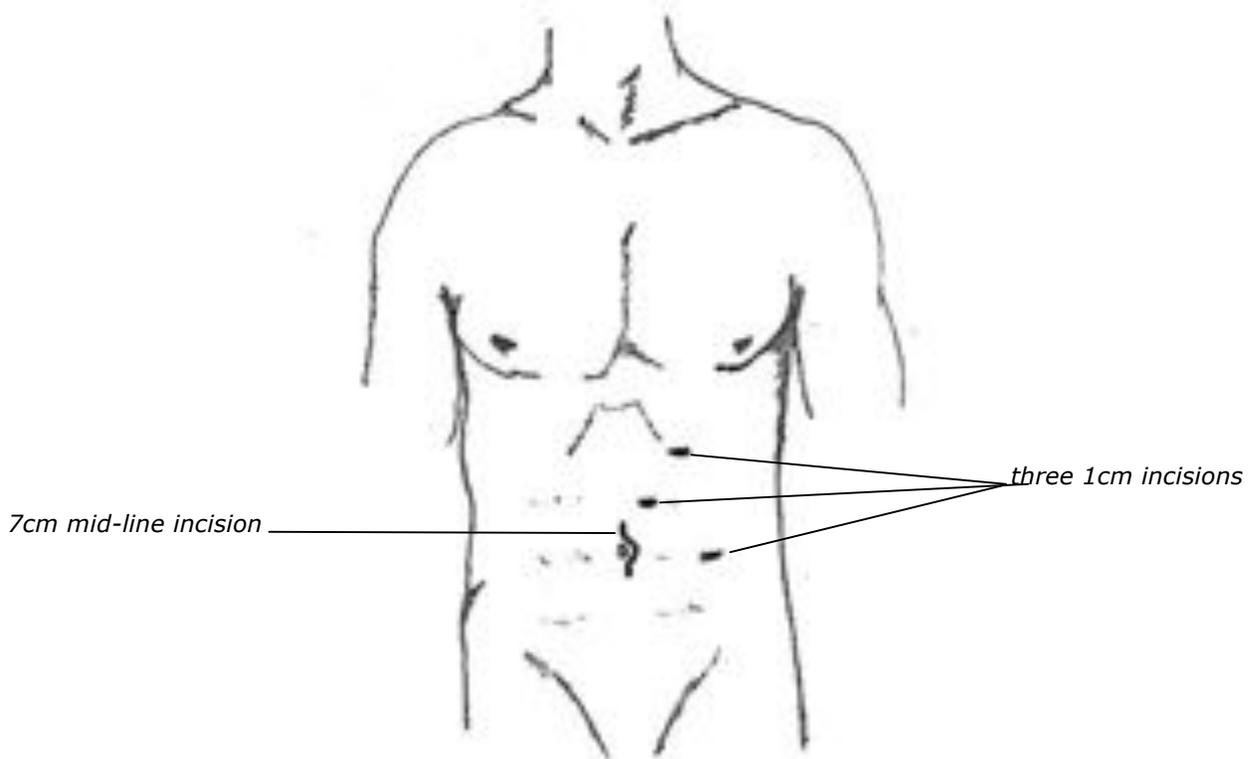
**Operative Approach:**

The operative approach (retrieval of either your left or right kidney) is chosen based on your kidney anatomy. There are currently two operative approaches in use. The best approach for you will be determined by the surgeon.

**1. Laparoscopic Hand Assisted Nephrectomy (kidney retrieval).**

This approach is used when the left kidney is chosen for donation. On occasion, the right kidney may also be removed using this technique but will depend on the anatomy.

This operation consists of removing your kidney through a small incision measuring 7 – 8cm in the midline around your belly button and three 1cm incisions on the right side of the abdomen as shown.

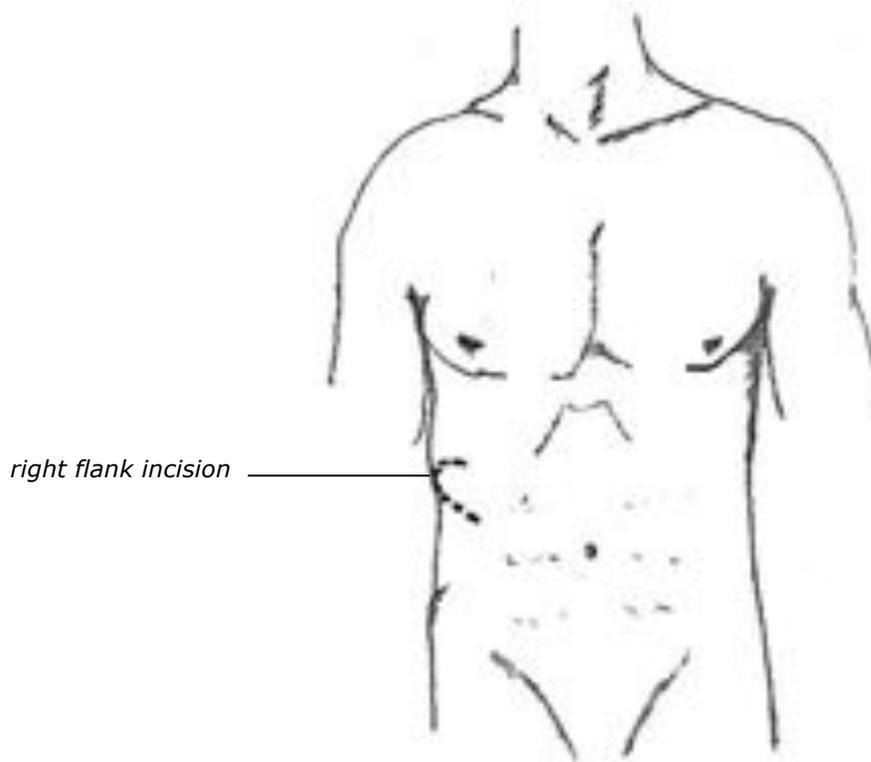


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## 2. Open donor nephrectomy (kidney retrieval).

This approach is used when the right kidney is chosen for donation by the surgeon.

This consists of a single incision measuring about 10 cm on your right flank, just under the ribcage.



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## **Preparing for Surgery**

**The Day Before Surgery:** In the morning, on the day before your scheduled surgery, you will be asked to go to the Tissue Typing Lab to give blood for the final crossmatch with your recipient. If this test demonstrates that you are no longer compatible with your recipient, we will need to cancel your surgery at the last minute. You will receive further instructions on diet and preparation. Remove your jewelry and leave your valuables for safe keeping at home. Bring only minimal belongings such as some clothes to change into when you are discharged home and a few toiletries.

**The Day of Surgery:** If the cross match results are satisfactory you will be admitted to the hospital at 0600am on your scheduled surgery date. You will be taken to the pre-op area where you will be able to greet your loved one. The operating room nurses, the anesthesia staff and surgeon will give you a final check before surgery.

You will then be taken into the operating room where we will start your surgery. In the next room, another surgeon will start surgery on your loved one in preparation to implant the new kidney. Both operations will occur simultaneously.

Your surgery will last about four hours. You will then spend another couple of hours in the recovery room. After anesthesia has safely worn off, you will be transferred to our general surgical ward.

**Hospital Stay:** Most patients should expect to stay in the hospital for two to three days after surgery. Some pain is normal and you will receive intravenous pain medications to relieve pain during your hospitalization. You will be given breathing exercises to prevent pneumonias and will need to walk around frequently to prevent blood clots in the legs. You will be started on a liquid diet soon after surgery when your intestines start to work. If you tolerate liquids then your diet will be advanced to regular diet over the next few days.

At discharge you will be given a prescription for pain medicines which should be filled at the hospital pharmacy at no cost to you. No prescriptions can be filled at outside pharmacies without you incurring a cost. You should not need any medications specific to kidney donation for long term use.

**Post-op Expectations and Instructions:** After donating a one kidney, the other will grow and compensate allowing the donor to live a full, active life. You must allow ample time to recover from surgery. Most people return to light activity immediately after surgery. Abdominal gas and bloating is common and even some shoulder pain but usually dissipates in a few days. There

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may be some incisional discomfort. Loose clothing is recommended. No lifting more than 10 to 20 pounds is allowed for 6 to 8 weeks. By this time the incision should be healed and you will be less likely to get a hernia. Walking, stair climbing and light activity is allowed during this time. Driving is prohibited until you have stopped taking all pain medicines and your surgeon permits you to resume driving. You may shower after the first couple days but you should avoid full immersion in the tub for about a week. Your wound will be closed with dissolvable sutures beneath the skin and skin glue.

**Post-operative Follow-up:** You will be scheduled for a follow up visit with your surgeon about one week after discharge (about two weeks from the date of surgery). You will also get labs within two weeks after surgery so that we can monitor you. After this, you will be discharged to the care of your primary care physician. Females should wait at least 6 months for kidney function to stabilize before becoming pregnant. You should refrain from sexual intercourse for a couple of weeks until you have less pain and have regained your strength and flexibility. We advise that you not travel outside the United States until you receive clearance from our surgeons.

As part of our **Long-Term Follow-up Care Plan**, you will be given orders for labs to be done at 2 weeks, 6 months, 12 months and again at 24 months. You should have routine health maintenance checks yearly by your primary care physician, this should include routine chemistry, urinalysis and blood pressure checks. Please send us your results. Transplant Centers are required to report living donor follow-up information for at least 2 years after donation to the United Network for Organ Sharing. If you have specific concerns about complications related to the donation process please contact our center.

**Concerns or Grievances**

You can contact the Clinical Director Nancy Johnson at 305-355-5225 to discuss any problems you may be experiencing with the transplant center or the system.

The United Network for Organ Sharing (UNOS) provides a toll free patient service line to assist transplant candidates, recipients, living donors and family members with understanding the organ allocation practices and transplantation data. You may also call this number to discuss a problem you may be experiencing with your transplant center or the system in general. The toll-free number is 1-888-894-6361.

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**Useful Resources:**

- Miami Transplant Institute website; [www.Miamitransplant.com](http://www.Miamitransplant.com)
- Please visit this link sponsored by the American Society of Transplantation:  
<http://www.healthy-donor.com/>
- United Network of Organ Sharing ; "Living Donation-Information You Need to Know";  
[www.unos.org](http://www.unos.org); [www.Transplantliving.com](http://www.Transplantliving.com)
- Read the brochure "Sharing Life: A guide to living donor kidney transplant";  
[www.TransplantExperience.com](http://www.TransplantExperience.com); or [www.DonateLife.org](http://www.DonateLife.org)
- View a 30-minute video from the American Society of Transplant Surgeons: "Kidney Transplantation: A Guide for Patients and their Families, Living Kidney Donation: What You Need To Know"; [www.ast.org/Research Education/Patient\\_education.aspx](http://www.ast.org/Research_Education/Patient_education.aspx)
- Listen to a Podcast: "Asking for a Living Donation" from the Beth Israel Deaconess medical center; [www.bidmc.org](http://www.bidmc.org); click on Your Health, BIDMC Interactive, Podcast Gallery, Channel Lineup-Transplant)
- Donate Life (U.S. Department of Health and Human Services website for organ and tissue donation and transplantation); [www.organdonor.gov](http://www.organdonor.gov)
- National Kidney Foundation; [www.kidney.org](http://www.kidney.org)

**Financial Resources:**

- National Living Donor Assistance Center: [www.livingdonorassistance.org](http://www.livingdonorassistance.org)

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**Important Numbers to Remember:**

**Support Staff:**

Cristina Gonzalez (305) 355-5241  
Lina (Marcy) Giraldo-Gonzalez (305) 355-5241

**Nurse Practitioner/Living Donor Advocate:**

Cherrie Cuffy, A.R.N.P. (305) 355-5311

**Clinical Nurse Coordinator/Living Donor Advocate:**

Maria Mithavayani, R.N. (305) 355-5230

**Clinical Director/Living Donor Advocate:**

Nancy Johnson, R.N., B.S.N. (305) 355-5225

**Social Worker:**

Jennifer Gonzalez, M.S.W. (305) 355-5288

**POST-OPERATIVE EMERGENCY ANSWERING SERVICE:**

**(305) 447-7645**

***(After-hours, weekends and holidays.)***

**A post-transplant coordinator will return your call and assess your emergency. The donor surgeon will be notified of the event.**

\_\_\_\_\_  
**Patient Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Physician Signature**